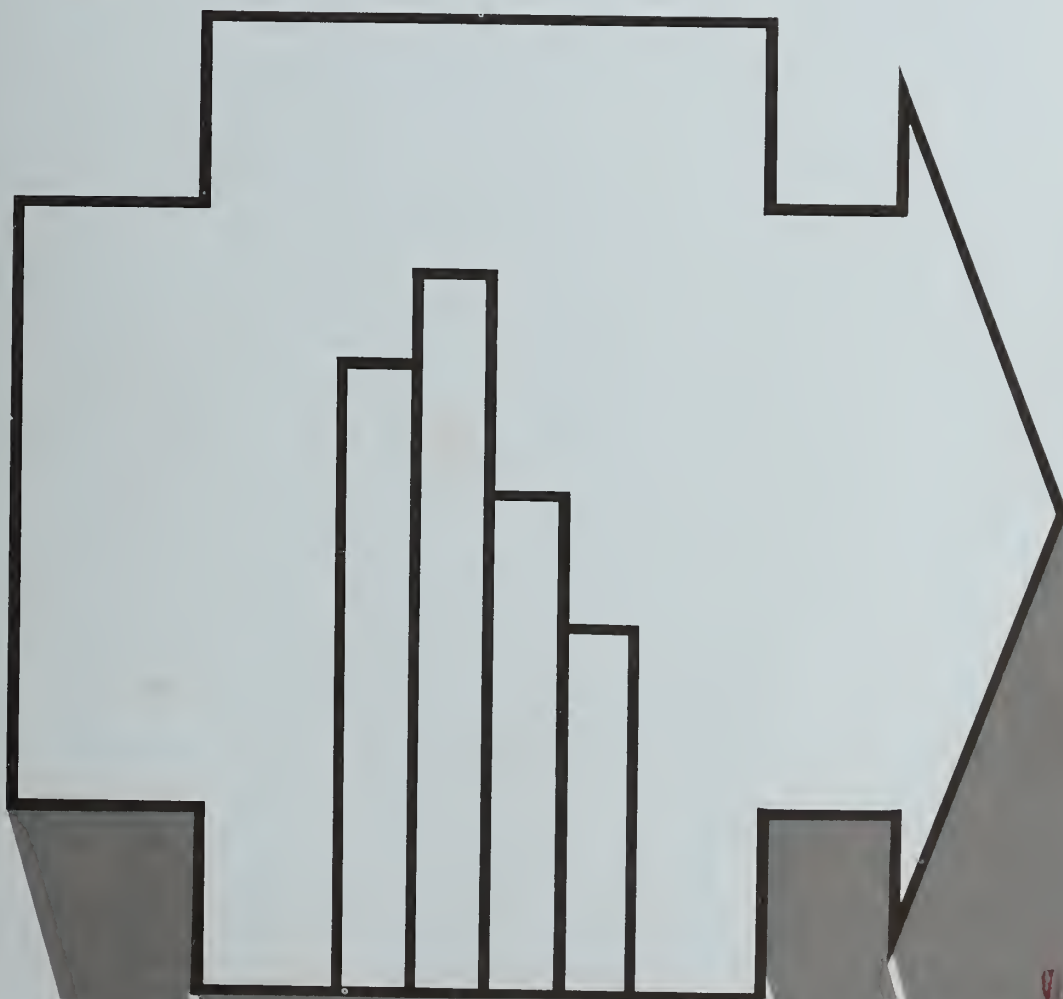


Medicare Annual Report

Fiscal Year 1983



PUBS
RA
412
.3
A323
1983

Information
Resource
Center

MEG 10.9

Medicare Annual Report

Fiscal Year 1983



RA
412.3
.A323
1983

SEVENTEENTH ANNUAL REPORT

ON MEDICARE

COVERING FISCAL YEAR 1983

INCLUDING REPORTS ON THE

REPORT ON MEDICARE/MEDICAID VALIDATION
SURVEY OF HOSPITALS ACCREDITED BY THE
JOINT COMMISSION OF ACCREDITATION
OF HOSPITALS

MEDIGAP VOLUNTARY CERTIFICATION PROGRAM

END STAGE RENAL DISEASE PROGRAM

DEPARTMENT OF
HEALTH AND
HUMAN SERVICES

HEALTH CARE
FINANCING
ADMINISTRATION

TABLE OF CONTENTS

	<u>PAGE</u>
Executive Summary.....	i
Legislation Enacted in FY 83.....	ii
PART I CHAPTER I PROGRAM OPERATIONS.....	iii
CHAPTER II PROGRAM ADMINISTRATION.....	iv
CHAPTER III RESEARCH, DEMONSTRATIONS AND STATISTICS.....	xiii
PART II END STAGE RENAL DISEASE (ESRD).....	xv
Introduction.....	2

Part I ANNUAL REPORT ON MEDICARE

Chapter I - PROGRAM OPERATIONS

A. Beneficiaries.....	3
B. Health Care Resources.....	3
C. Benefit Payments.....	4
D. Claims Processing Performance.....	6
E. Contractor Administrative Cost Experience.....	10
F. Program Funding.....	11
G. Contractor Performance Evaluation Program (CPEP).....	12

Chapter II - PROGRAM ADMINISTRATION

A. Summary of Administrative Structure.....	14
B. Achieving More Efficient Intermediary and Carrier Performance.....	17
C. Reimbursement Controls/Policy Initiatives.....	26
D. Improving Utilization Safeguards.....	41
E. Quality and Appropriateness of Care.....	44
F. Report on Medicare/Medicaid Validation Survey of Hospitals Accredited by The Joint Commission on Accreditation of Hospitals	47
G. Increasing HMO Enrollment by Medicare Beneficiaries.....	54

TABLE OF CONTENTS

	<u>PAGE</u>
H. Payments to Health Maintenance Organizations and Competitive Medical Plans.....	55
I. Fraud and Abuse Control Activities.....	57
J. Beneficiary Services.....	65
K. Medigap Voluntary Certification Program	68
L. Implementation of the Prospective Payment System.....	72
M. Operational Review Activity.....	73
Chapter III - REPORT ON RESEARCH, DEMONSTRATIONS AND STATISTICS.....	74
Appendices	
A. Part A Intermediaries and Part A Blue Cross Plans.....	96
B. Part B Blue Shield Plans and Part B Commercials, Other.....	100
C. Program Data by States.....	102
D. Five-Year Trend Analysis of Contractor Administrative Costs and Productivity Improvements.....	103
E. Significant Legislation Enacted During FY 83.....	107
PART II	
END STAGE RENAL DISEASE (ESRD) PROGRAM - 1983	
Chapter I - GENERAL	
A. Scope of Report.....	128
B. ESRD Highlights.....	129
C. ESRD Program Growth.....	131
D. Data Collection.....	132
Chapter II - FACILITIES	
A. ESRD Facilities Surveyed and Reporting by State in 1983.....	134
B. Number of Certified ESRD Facilities since 1973.....	135
C. Dialysis Facilities, Hospital - 1983.....	136
D. Dialysis Facilities, Independent - 1983.....	137
E. Type of Ownership - Profit vs. Non-profit - 1983.....	138
F. Minimum Utilization Rate Status of Facilities.....	139
G. Minimum Utilization Rate Status-Dialysis-1983.....	140
H. Transplant.....	141
I. Minimal Utilization Rate Study.....	142

TABLE OF CONTENTS

	<u>PAGE</u>
 Chapter III - DIALYSIS	
A. Dialysis Patient Profile (Total, Incenter, Home, Self-Care)....	144
B. New Patient Characteristics (Total, Incenter, Home, New Starts).	151
C. Continuous Ambulatory Peritoneal Dialysis (CAPD) National Patient Registry.....	153
 Chapter IV - TRANSPLANT	
A. Summary of Transplant Activity.....	156
B. Transplants Performed During 1983 - By State.....	157
C. Transplant Types By Network - 1983.....	158
D. Transplants 1982 - 1983.....	159
E. Patients Awaiting Transplants vs Transplants Performed.....	160
F. Transplant Failures.....	161
G. Range of the Number of Transplants Performed.....	161
H. ESRD Network Distribution of Transplants Arrayed by Number of Transplants Performed.....	162
 Chapter V - COST	
A. Hospitalization for Ancillary Problems.....	164
B. Kidney Acquisition Costs and Charges.....	166
C. Independent Organ Procurement Agencies.....	170
D. Dialysis Payment Rates.....	171
E. Exception System.....	172
F. Transplant Procedures.....	175
G. Physician Services	175
H. Projected Enrollment and Benefit Payments for the ESRD Program.....	177
 Chapter VI - ESRD STATISTICS	
A. End-Stage Renal Disease (ESRD) Program Survival Analysis.....	180
B. Medicare Inpatient Hospital Use, by Age Interval, 1983.....	187
C. Ratio of Patients Trained for Home Dialysis and Dialysis Patients Transplanted to Average Number of Dialysis Patients, 1979-1983...	188
D. Major Reasons for Changes in the Number of Patients Treated by Medicare Certified Suppliers of ESRD Services, 1979-1983.....	189
 Chapter VII.- MISCELLANEOUS	
A. Cost-Savings and Other ESRD Experiments.....	192
B. Results of Basic Kidney Disease Research.....	211
C. ESRD Network Organizations.....	228
D. Appendix - Tables and Figures.....	230

EXECUTIVE
SUMMARY
1983

ANNUAL REPORT ON MEDICARE

EXECUTIVE SUMMARY

This annual report describes the performance of the Medicare program during its seventeenth year. This report is divided into two parts: Part I, which provides an update on the Medicare program based on fiscal year 1983 activities and includes, Chapter I Program Operations, Chapter II Program Administration, which includes a Report on Medicare/Medicaid Validation Survey of Hospitals Accredited by the Joint Commission on the Accreditation of Hospitals and Medigap Voluntary Certification Program, Chapter III Research, Demonstrations and Statistics; and Part II, which reports on the End Stage Renal Disease program in calendar year 1983. These reports are mandated by the Social Security Act, as amended: Section 1875(b) mandates an annual report on Medicare activities, Section 1881 (g) mandates the report on the End Stage Renal Disease Program on July 1, 1979 and each July 1 thereafter, and Section 1882 (f) (2) requires a report on Medigap activities "no later than July 1, 1982, and periodically as may be appropriate thereafter (but not less often than once every 2 years)."

LEGISLATION ENACTED IN FY 83

During Fiscal Year 1983, six laws were enacted which contained significant Medicare-related provisions. A list of these measures follows and a discussion of their provisions of interest is provided at Appendix E.

P.L. 97-248: The Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). Subtitle A made significant changes in both Part A and Part B of Medicare. Subtitle E subjected federal employees to the Medicare tax. Subtitle C. of this Act, The Peer Review Improvement Act of 1982, authorized the establishment of Utilization and Quality Peer Review Organizations to supersede PSROs.

P.L. 97-414: Orphan Drug Act. Amended the Public Health Service Act to authorize grants and loans to encourage the establishment and initial operation of home health programs and home health training programs in areas in which such services were not provided. Required the Secretary of HHS to study and report to Congress on various aspects of the home health issue, including reimbursement alternatives for home health agencies and methods to stem fraud and abuse in the Medicare and Medicaid home health programs.

P.L. 97-448: Technical Corrections Act of 1982. Clarified the definition of Medicare-qualified Federal employment, directed the Secretary to disregard Professional Standards Review Organizations evaluations for two quarters during FY 1982, and exempted HCFA hospice demonstration projects from the requirement to furnish certain core services directly.

P.L. 97-455: Virgin Islands Tax Reduction Act. Permitted disability insurance beneficiaries to elect to retain Medicare coverage while appealing a decision to terminate disability benefits to an administrative law judge and gave the Secretary of HHS discretion to reduce the flow of continuing disability investigations on a state-by-state basis.

P.L. 98-21: Social Security Amendments of 1983. Established a new reimbursement system under Part A of Medicare in which inpatient hospital operating costs are paid for on a prospective determined per case basis for specific medical conditions or combinations of conditions known as diagnosis related groups.

P.L. 98-90: To increase the cap amount allowable for reimbursement of hospices under the Medicare program. Raised the Medicare cap to \$6,500 per patient and permitted adjustment of the cap in future years according to annual changes in the medical care component of the Consumer Price Index.

PART I

CHAPTER I PROGRAM OPERATIONS

Beneficiaries - As of July 1, 1983, 27.1 million aged persons and 2.9 million disabled persons under 65, a total of 30.0 million, were entitled to hospital insurance (Part A) and/or supplementary medical insurance (Part B). Of the 30.0 million enrollees, 29.6 million had Part A and 29.0 million had enrolled in Part B. Of beneficiaries aged 65 and over, 95 percent were covered by both Part A and Part B; 92 percent of disabled beneficiaries were covered by both parts.

Health Care Resources - As of July 1, 1984, there were 6,675 hospitals participating in Medicare with 1,144,142 beds. There were 5,952 skilled nursing facilities, 4,684 home health agencies, 3,801 independent laboratories and 1,334 facilities or units providing services to program beneficiaries requiring maintenance dialysis or kidney transplant. Additionally, 420 rural health clinics, 155 ambulatory surgical centers, and 108 hospices were certified to participate in the program.

Benefit Payments - During FY 83, Medicare paid \$38.1 billion in benefits under hospital insurance (Part A) and \$17.5 billion under medical insurance (Part B). These amounts represent an increase of 10.9 and 18.1 percent over FY 82 payments of \$34.3 billion and \$14.8 billion, respectively. Inpatient hospital care accounted for 95 percent of all Part A payments. Physician and other Part B suppliers' services accounted for 74 percent of Part B payments.

Claims Processing Performance - Claims received by intermediaries increased to 50.6 million in FY 83, an increase of 7.0 percent over the FY 82 experience. Claims received by carriers rose at a rate of 10.7 percent, totaling 208.4 million in FY 83. Overall, the volume of Medicare claims rose 9.9 percent. The average claims processing time for intermediaries decreased from 8.4 days to 7.0 days. Carriers showed a decrease in yearly average claim processing time from 10.5 days to 9.9 days. The average monthly percentage of bills pending over 30 days for intermediaries decreased from 13.7 to 11.6 percent. Carriers' average percentage of bills pending over 30 days decreased from 11.2 to 9.9 percent.

Contractor Administrative Cost Experience - The FY 83 intermediary workload processed was 6.9 percent higher than in FY 82. The total cost increased 7.0 percent. The unit cost for all operations increased by 29 cents. The increase was due to increased audit efforts. For Carriers, the processed workload increased by 9.8 percent. The unit cost decreased by 9 cents during FY 83 and the total cost increased by 5.9 percent.

Program Funding - The primary source of hospital insurance (Part A) financing is contributions, based on earnings, by workers and their employers, and by self-employed individuals. The remainder is derived from general revenues and other sources. Medical insurance (Part B) is financed by three sources: (1) premium payments from enrollees, (2) contributions from general revenues, and (3) interest on trust fund accumulations.

Rural Health Clinics - The Rural Health Clinic (RHC) Act was passed in the hope that defining this benefit under Medicare and Medicaid to allow payment for services, rendered by physician assistants and nurse practitioners, in RHC settings would expand the access to care for people in health under serviced rural areas. In FY 1983 \$4,296,398 in Medicare benefits was paid to Rural Health Clinics (RHC). Administrative costs for RHC Medicare services were \$963,702 which represents a 3 percent decrease from FY 1982. Medicare intermediaries processed 247,127 RHC claims from an average of 418 RHC's.

PART I

CHAPTER II PROGRAM ADMINISTRATION

Administrative Structure - The overall responsibility for administration of Medicare is vested by law in the Secretary of the Department of Health and Human Services (DHHS). Primary responsibility for administering the Medicare program is assigned to the Health Care Financing Administration (HCFA). The Social Security Administration is involved in the enrollment of beneficiaries in the program and other beneficiary related activities. The Department's Public Health Service (PHS) acts as a valuable resource in the professional health aspects of the Medicare program. The Office of Civil Rights is responsible for assuring compliance with Title VI of the Civil Rights Act of 1964. The Secretary also uses the services of appropriate State or local health agencies to ascertain whether providers of service and independent laboratories meet the conditions for participation in the Medicare program. Intermediaries (Part A) and carriers (Part B) contract with the Federal government to reimburse providers for services rendered to beneficiaries and to provide other services, in accordance with their agreements.

Intermediary and Carrier Performance - During FY 1983, HCFA evaluated the performance of Medicare contractors using the Contractor Performance Evaluation Program. In this program, specific standards and criteria were applied to all carriers and intermediaries. As a result, 10 Medicare contractors were identified as poor performers based on their performance during FY 1983.

Contracting Initiatives and Experiments - Under Section 222 of P.L. 92-603, HCFA was granted experimental authority to test incentive contracting for intermediary and carrier administrative functions. Under an incentive contract, intermediaries and carriers are reimbursed on a basis other than on actual costs incurred. They are at risk and may suffer monetary damages for failure to meet performance objectives. In addition, certain fixed price contractors also may receive incentive payments if their performance exceeds contractual requirements. As a result of assuming the risk of non-performance, intermediary or carrier internal management is responsible for improved efficiency and economy in operations. HCFA has taken action in the experimental contracts to assure that a continuing high level of service to Medicare beneficiaries and providers is maintained. In each experimental contract, performance requirements have been introduced which exceed those applied to the incumbent contractors reimbursed on a cost basis.

The use of incentive contracts on an experimental basis, authorized by Congress in 1972, is a departure from the basic statutory authority directing HCFA to reimburse contractors for the necessary and proper cost of administration of their contract duties. The experimental contracts utilize selected performance standards and existing quality control and performance review procedures and provides for the assessment of liquidated damages if the contractor fails to meet the standards established. Evaluations are made of actual performance against the standards and are completed on a quarterly basis by regional office staff.

Improving Utilization Safeguards - One of the most critical areas of Medicare program activity is to establish safeguards against improper and excessive utilization of health care services. The program has approached its responsibilities in this area in a number of ways, with its structure providing some fundamental controls. For example:

Deductible and coinsurance amounts.

Services furnished on a physician's order under direction of a physician.

Service reasonable and necessary for the diagnosis and treatment.

For home health services, physicians are prohibited from certifying the need for such services and establishing a plan of care if they have a significant ownership interest or significant contractual or financial interest in the home health agency.

HCFA has continued to refine the pre- and post-payment screens which intermediaries and carriers utilize to identify situations of potential overutilization or variations from medical necessity norms.

REIMBURSEMENT CONTROLS/POLICY INITIATIVES

In FY 83, new approaches were initiated in both the legislative and administrative areas to curtail program cost increases and maintain quality and accessibility to health care services for program beneficiaries. The most significant included:

Reasonable Cost Limits - Initially, provider reimbursement included all necessary and proper expenses incurred in the delivery of patient care. However, reimbursement based on incurred costs did not offer sufficient incentives to control the rapid escalation of health care expenditures. Section 223 of the Social Security Amendments of 1972 (P.L. 92-603) amended the definition of reasonable cost to exclude costs determined to be unnecessary in the efficient delivery of needed health services. Subsequent legislation authorized the establishment of prospective cost limits based on provider classification and reduced the level of cost limits for hospitals and other providers.

In FY 83, Medicare hospital reimbursement reform rules were implemented under the provisions of section 101 of the Tax Equity and Fiscal Responsibility (TEFRA) Act of 1982 (P.L. 97-248 enacted September 3, 1982). The new rules changed the overall limits on reimbursable hospital costs and established a new process to limit the rate of hospital cost increases. Effective with the beginning of FY 83 a new schedule of overall limits on hospital inpatient operating costs was published along with new rules establishing a three year ceiling on allowable annual rates of increase in inpatient operating costs. The new limits differed from the earlier per diem limits in several major respects.

The limits are expanded to include special care and ancillary costs as well as general routine costs. Adjustments are made for differences in the mix of cases handled by each hospital. Although hospitals cannot be paid more than the overall cost limits, those that incur costs lower than their rate of increase ceiling will be paid a portion of the difference, while hospitals that exceed the target ceiling are paid the target amount plus 25 percent of the excess amount for the first two years of the program.

Regulations and program instructions which immediately applied these new limits to Medicare reimbursement amounts and allowed identification of hospital types to be excepted from the new limits were published in September and October, 1982.

Hospital Prospective Payments - In December 1982, a report to Congress was submitted pursuant to section 101 of P.L. 97-248 which provided a legislative proposal for establishing a fully prospective payment system for Medicare payments to hospitals. The proposal, in general, was to base payment for all hospital inpatient costs on a diagnosis related group (DRG) coding, adjusted by case mix, excluding capital-related and direct medical education costs and excluding certain types of hospitals and units. The Congress quickly acted on the proposal, expanded its major features and it was enacted as part of the Social Security Amendments of 1983 on April 20 as P.L. 98-21. Major features of the new prospective payment system (PPS) to be implemented beginning with hospital fiscal years beginning on or after October 1, 1983 (FY 84) included a phase-in period of three fiscal years during which

time hospitals would be paid a blended PPS rate which was comprised of a Federal (DRG) standardized portion and a hospital-specific portion, special adjustments for certain classes of hospitals, medical review activities, budget neutrality vis-a-vis TEFRA levels of payment and rebundling of nonphysician service costs into hospital inpatient costs either directly or under arrangement where hospitals had previously allowed such services to be provided and billed by outside activities. Program instructions were published in May and August, 1983, while regulations were proposed and issued on September 1, 1983 in order to implement the totally new Medicare hospital payment system beginning October 1, 1983. (Final regulations implementing the program were issued on January 3, 1984.)

Inpatient Routine Nursing Salary Cost Differential - The provisions of section 103 of P.L. 97-248, eliminating the inpatient routine nursing salary cost differential were implemented by the October 1, 1982 publication in the Federal Register of a final rule with comment period (47 FR 43618). This amendment was effective for cost reporting periods ending after September 30, 1982.

OTHER POLICY INITIATIVES/ISSUES

Other Coverage Issues

Medicare Coverage of Heart Transplantation - A broad study of all aspects of medical coverage of heart transplantation, including social, economic, and scientific issues is underway; its results will be used in the development of a national coverage policy on heart transplantation. Heart transplantation is now excluded from Medicare coverage on the grounds that it has not been demonstrated to be a safe and effective procedure.

Medicare Coverage Decision Procedures - HCFA's process for developing national coverage policy determinations as to whether health care items and services are "reasonable and necessary" under the law has continued to improve. The HCFA Physicians Panel, which helps develop national coverage policy determinations as to whether health care items and services are "reasonable and necessary" under the law, met regularly to discuss and advise on new and unusual questions, and to recommend referral of selected questions to the Public Health Service for medical and scientific advice and recommendations.

Confidentiality and Disclosure - HCFA prepared a final rule to change the location of certain regulations that concern the availability of Medicare information and records to the public from 20 CFR Part 422 to 42 CFR Part 401. HCFA changed its policy to allow disclosure of identifiable information without beneficiary consent to an individual or organization for epidemiological and other research and statistical purposes provided certain specific criteria and safeguards are met.

Provider Reimbursement Appeals - Section 955 of P.L. 96-499 amended Section 1878(f)(1) of the Social Security Act. The amendments make it possible for a provider that requests and has the right to obtain a hearing by the Provider Reimbursement Review Board (PRRB) under Section 1878(a) of the Act, to bypass the hearing and obtain judicial review of any action of the fiscal intermediary that involves a question of law or regulations relevant to the matters in controversy, whenever the PRRB determines that it is without authority to decide the question. The PRRB may determine that it does not have the authority, either on its own motion or upon the request of a provider.

HCFA published a regulation on May 23, 1983 detailing the procedures by which a provider may bypass the PRRB hearing.

Waiver of Liability Procedures Applicable to Erroneous Placement in an Inappropriately Certified Bed of a Participating Hospital or Skilled Nursing Facility (SNF) - Section 956 of P.L. 96-499, effective January 1, 1981, amends Section 1879 of the Social Security Act to permit program payment for an otherwise qualified Medicare beneficiary who is precluded from Medicare reimbursement solely because services were received in a part of an institution not qualified to provide the appropriate level of care. This provision applies to hospital and SNF levels of care. Appropriate implementing instructions were issued to contractors and providers.

Quality and Appropriateness of Care - A major goal of the Medicare program is to assure that its beneficiaries receive appropriate health services. Additionally, HCFA must ensure that services are necessary and performed at the most economical level consistent with good care. These goals are met through HCFA's standards and certification on peer review activities.

Standards and Certification - Facilities providing health care services to Medicare beneficiaries must meet certain health and safety standards before they can receive Medicare reimbursement. Surveys are conducted by States under contract with the Department with all long-term care facilities and approximately 50 percent of all other facilities surveyed annually. However, the Social Security Act allows the privately run Joint Commission on Accreditation of Hospitals (JCAH) and the American Osteopathic Association's (AOA) standards and certifications to be considered as having met the Federal government's requirements. Therefore, States only survey those hospitals not accredited by JCAH or AOA and will, on a sample basis, conduct surveys on JCAH or AOA hospitals in order to validate that the surveys conducted by those associations continue to meet Medicare requirements.

Generally, the Federal Standards and Certification program is responsible for establishing and updating Federal health care standards, developing State survey procedures, and monitoring surveys and enforcement. This report includes discussion of major FY 81 activities in the following areas:

Hospital Conditions of Participation

Skilled Nursing Facility/Intermediate Care Facility Conditions of Participation

Survey and Certification Procedures (Subpart S)

Fire Safety Evaluation System

Conditions of Coverage for Suppliers of Laboratory Services

JCAH Validation Process

Professional Standards Review Organizations (PSROs) - As a result of the Omnibus Budget Reconciliation Act of 1981, PSRO's were no longer required to perform Medicaid reviews, as of October 1, 1981 but were still required to review those health services provided to Medicare patients. State Medicaid agencies were given the option of contracting with PSRO's for the continued performance of medical or utilization review functions and therefore be deemed to meet the Utilization Control (UC) requirements for those services and providers that the PSRO reviews, or States could assume direct responsibility for assuring the UC required by Title XIX of the Social Security Act. Any agreements entered into with the PSRO prior to October 1, 1981 continued to exist until the next renewal date of the agreement or in accordance with the instructions in the existing grant. During FY 83, HCFA developed plans and initiated program/policy activities to replace PSROs with Utilization and Quality Control Peer Review Organizations (PROs) pursuant to the Peer Review Improvement Act of 1982 (subtitle C. of TEFRA - P.L. 97-248).

Second Surgical Opinion Program - In FY 1978, HCFA began a major consumer information campaign to encourage all Americans to seek a second opinion before undergoing non-emergency surgery. The campaign is directed toward the general public. Publicity to promote the program included radio and T.V. spots, articles distributed to major publications, and cooperation with insurance companies. Much of the publicity was directed in promoting the Hotline number (800-638-6833). In FY 1983 eight million brochures entitled "Thinking of Having Surgery? Think About Getting a Second Opinion" were distributed.

Increasing HMOs Enrollment by Medicare Beneficiaries

Health Maintenance Organizations (HMOs) are a growing alternative to traditional forms of health care delivery. An HMO is an organization which provides its members comprehensive health services, without regard to frequency or extent of services, in return for predetermined, fixed premiums paid by members. During FY 83, 12 HMOs signed contracts to enroll Medicare members. This brought the total of contracting HMOs to 75. Medicare membership in HMOs increased during FY 83 from 127,606 to 192,830 or approximately 51 percent.

Fraud and Abuse Control Activities

In January 1983, the Medicare fraud and abuse functions, formally located within HCFA, were transferred to the Office of the Inspector General (OIG). Future figures regarding the areas on fraud, abuse, investigations, overpayments and savings will be reported by the OIG in their semi-annual report to Congress. The administrative sanction authority was also transferred to the OIG in January 1983. Data regarding this authority will also be reported semi-annually to Congress.

BENEFICIARY SERVICES

Established in December 1979, the primary objectives of the Office of Beneficiary Services (OBS) are:

1. Inform beneficiaries about HCFA programs, and their rights and responsibilities.
2. Open channels of communication between beneficiary representative groups and HCFA.
3. Improve services provided to beneficiaries by contractors, State agencies and Social Security offices.

Updating, Revising, and Improving Beneficiary Informational Material

OBS revises and updates Your Medicare Handbook semi-annually and some 20 other Medicare pamphlets at least annually. Six million copies of Your Medicare Handbook were printed and distributed to Social Security Offices, Medicare contractors and new Medicare enrollees during FY 1983.

OBS also helps the public stay informed about current changes through Medicare/Medicaid Notes which is a monthly fact sheet explaining specific issues or recent changes in Medicare or Medicaid policy and procedures. This is distributed to all HCFA regional offices and approximately 40 National organizations (e.g., American Association of Retired Persons and National Council of Senior Citizens which have publications or newsletters for their members).

Medigap

HCFA has developed an education program to better inform Medicare beneficiaries about (1) Medicare coverage, (2) the major gaps in Medicare coverage, (3) the various types of private health insurance designed to supplement Medicare and (4) comparative shopping hints to use when purchasing private supplemental health insurance. To implement this initiative, OBS designed, developed, and produced the 68-page training text, Medicare and Private Health Insurance, based on a pamphlet developed jointly with the National Association of Insurance Commissioners (NAIC). This text, plus accompanying visual aids and a checklist for comparing policies, serves as the basic material for a nationwide program to train counselors and volunteers who, in turn, assist Medicare beneficiaries on private health insurance decisions. To date, HCFA regional office Medigap coordinators (who received their initial Medigap training at central office) have conducted more than 709 training sessions in all 50 States, the District of Columbia and Puerto Rico. Approximately 35,141 attendees have received Medigap training through this program. A continuation of another facet of the Medigap initiative has been the distribution of over 9 million copies of A Guide to Health Insurance for People with Medicare, the information pamphlet which was first produced in 1979 in conjunction with NAIC.

Liaison With Beneficiary Organizations

OBS maintains an ongoing program of liaison with beneficiary organizations. In addition to soliciting beneficiary organization input and participation in the development of program policy and procedures through briefings and personal liaison, OBS periodically mails materials to national beneficiary groups to keep their membership informed about current Medicare benefits and coverage. OBS representatives also attend national organization conferences and meetings, and participate in workshops, panel discussions and forums on Medicare-related issues.

Beneficiary Casework

OBS continued to function as a central office ombudsman for special beneficiary inquiries and problem cases. Most inquiries are telephone referrals from the HCFA Office of the Administrator, Office of the Secretary, HHS; the White House; and Congress. Many inquiries come directly from beneficiaries seeking help with errors in their records resulting in loss of eligibility or incorrect premium billings necessitating a review and correction of their Medicare records. There is also a high incidence of complaints about what are seen as deficiencies in program coverage; e.g., the lack of prescription drug or nursing home coverage under Medicare. In such cases, efforts are made to guide the caller to other resources for financing the necessary medical services. Other inquiries relate to difficulties with Medicare contractors and problems involving submission of, and reimbursement for, Medicare claims. In all these instances, the ombudsman function provides a valuable service for Medicare and Medicaid beneficiaries, many of whom have difficulty dealing with the complexities of these programs.

Beneficiary Services Awards

The Beneficiary Services Awards were established to provide special recognition to individuals or groups for either outstanding performance in service to beneficiaries or for a major contribution in the area of beneficiary services. The awards serve to provide an incentive to develop innovative ideas, resources, and programs in assisting beneficiaries.

HCFA again recognized outstanding beneficiary service awardees selected in FY 1983 as part of HCFA's Annual Awards Ceremony. A HCFA employee received the Beneficiary Services Cash Award, while the Beneficiary Service Certificate of Merit was presented to two HCFA employees and five non-government organizations and individuals for their contributions to the improvement of services in the Medicare and Medicaid programs. This final group of five non-government awardees represented Medicare contractors and beneficiary groups from four different States and the District of Columbia.

CHAPTER III RESEARCH, DEMONSTRATIONS, AND STATISTICS

Research and experimentation in support of the Medicare program is authorized in the Social Security Act and the Social Security Amendments of 1967, 1972 and 1983.

HCFA undertakes studies and demonstrations to develop ways to promote efficiency and quality in the Medicare and other HCFA programs. It assesses the impact of the programs on health care costs, program expenditures, beneficiary access to services, health care providers, and the health care industry. These research and demonstration projects also test and evaluate alternatives to present reimbursement, coverage, eligibility and management policies of the Medicare program.

During FY 83, HCFA conducted research, demonstration, and evaluation projects in the following seven program areas:

Hospital Payment

Physician Payment

Long-Term Care

Alternative Payment Systems

Program Analysis & Evaluation

Coverage

Prevention

Following the section on the research, demonstrations and evaluation projects, there is a brief discussion of HCFA's data base and statistical activities. There is also a discussion of the research and demonstration publication program. Copies of the publications are available from ORD Publications, Room 1-A-9 Oak Meadows Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

PART II
ANNUAL REPORT
ON THE
END-STAGE RENAL DISEASE PROGRAM
(CALENDAR YEAR 1983)

PART II
END STAGE RENAL DISEASE

The 1983 End-Stage Renal Disease (ESRD) report is prepared in accordance with Section 1881(g) of the Social Security Act, and addresses the 15 specific requests for data enumerated therein. It covers activities related to the care of ESRD patients that took place in calendar year 1983, and includes information on the number of patients utilizing the various forms of treatment, the costs involved, discussions of cost savings experiments, and basic kidney research conducted during the year.

The total dialysis population increased by 9.5 percent in 1983, to 71,987 from 65,765 in 1982. The home dialysis population increased by 16.3 percent, to 13,645 from 11,733 in 1982. The net increase in home patients was due largely to the growth of continuous ambulatory peritoneal dialysis (CAPD) from 6,523 patients in 1982 to 8,532 patients in 1983. CAPD now accounts for 62.5 percent of all home patients. At the end of 1983, the home dialysis population accounted for 18.9 percent of the total dialysis population, a net increase of 1.1 percent over 1982.

The number of patients receiving a transplant increased by 14.0 percent in 1983, to 6,112 from 5,358 in 1982. Patients transplanted in 1983 accounted for 8.5 percent of the total ESRD population, a net decrease of 1.5 percent over 1982. The percentage of total transplants performed with kidneys from living related donors increased 6.3 percent from 1982 figures, while cadaveric transplants increased 17.6 percent.

Total expenditures for services rendered during the calendar year were more than \$1.8 billion, based on bills posted as of December 31, 1984. The 1983 figure will increase as bills continue to be posted. The average payment rate for both hospital and freestanding dialysis units for dialysis was \$160 per treatment prior to August 1, 1983 when Section 2145 of P.L. 97-35 was implemented. Thereafter, the average payment rates per treatment were \$130.41 in hospital-based facilities and \$125.59 in independent facilities. This dual rate prospective payment system excludes physicians' fees. A monthly capitation payment system (MCP) has been used to pay physicians for their ESRD related professional services. The MCP was effective August 1, 1983 and replaced the initial method. The average kidney acquisition charge in 1983 was \$10,065 for a living related donor kidney and \$9,850 for a cadaveric kidney. The average estimated kidney acquisition costs were \$8,452 and \$8,298, respectively. The average estimated cost for a transplant in 1983 was \$27,144, excluding physicians' services.

PART I

ANNUAL REPORT ON MEDICARE
INCLUDING A REPORT ON THE

REPORT ON MEDICARE/MEDICAID
VALIDATION SURVEY OF HOSPITALS ACCREDITED
BY THE JOINT COMMISSION ON ACCREDITATION
OF HOSPITALS

MEDIGAP VOLUNTARY CERTIFICATION PROGRAM

INTRODUCTION

This annual report on Medicare, the seventeenth, describes program performance from October 1, 1982 through September 30, 1983. The additional reports mandated by Congress are a Report on Medicare/Medicaid Validation Survey of Hospitals Accredited by the Joint Commission on Accreditation of Hospitals (JCAH), and the Medigap Voluntary Certification Program.

In fiscal year 1983, the Federal government continued to place high priority on combating inflation and reducing public expenditures. Attention to these objectives is reflected throughout this report by the considerable emphasis on increasing operational efficiency of Medicare and improving the effective use of public funds for this major national health care program.

CHAPTER I. PROGRAM OPERATIONS

A. BENEFICIARIES

As of July 1, 1984, a total of 30.0 million beneficiaries were entitled to Medicare: 27.1 million aged persons and 2.9 million disabled persons under 65. Of the total beneficiaries, 29.6 million had hospital insurance (Part A), and 29.0 million had enrolled in the voluntary medical insurance program (Part B). Of beneficiaries age 65 or over, 95 percent were covered by both Part A and Part B while 92 percent of disabled beneficiaries were covered by both parts. Of all beneficiaries, 29.4 million resided in the United States, representing 13 percent of the U.S. resident population.

The number of aged persons entitled to Medicare as of July 1983 increased nearly 570,000 (from 26.5 million to 27.1 million) over the July 1982 enrollment. This increase reflects the continuing trend of the last decade in an annual net growth of over 2 percent in the age 65 and over segment of the U.S. population. In addition to growth in the number of aged, the average age of beneficiaries also increased. The proportion of beneficiaries age 85 and over increased from 7 percent in 1970 to 10 percent in 1982. In addition, there has been a 10 percent decline in the death rate of the 65 and older group from 1970 to 1980. The death rate in 1970 was 5,892 per 100,000 as compared to 5,291 per 100,000 in 1980. These factors contribute to more intensive use of Medicare-covered health care services over a longer period of time.

B. HEALTH CARE RESOURCES

As of July 1, 1983 there were 6,675 hospitals with 1,144,142 beds participating in Medicare compared to 6,737 hospitals with 1,143,699 beds as of July 1, 1982. Included in the participating hospitals were 6,038 short-stay hospitals, 433 psychiatric, and 204 other long-stay institutions. Ninety percent of the total number of beds are in short-stay hospitals, 9 percent in psychiatric institutions, and 2 percent in other long-stay institutions.

As of July 1, 1983, there were 5,952 skilled nursing facilities with 530,403 beds participating in Medicare, up from 5,632 facilities with 511,663 beds as of July 1, 1982. Participating facilities include skilled nursing facilities, separately organized extended care units in hospitals, and some separate skilled nursing units connected with residential homes for the aged.

The number of home health agencies participating in the Medicare program rose from 3,959 to 4,684 in the 12-month period ending July 1, 1983.

As of July 1, 1983, a total of 3,801 independent laboratories had been approved for Medicare reimbursement, up from 3,643 12 months earlier.

Under the renal disease program as of July 1, 1983, 1,334 facilities or units provide services to program beneficiaries requiring maintenance dialysis or kidney transplant.

C. BENEFIT PAYMENTS

During FY 83, Medicare paid \$38.1 billion in benefits under hospital insurance (Part A) and \$17.5 billion under medical insurance (Part B). These amounts represent an increase of 10.9 and 18.1 percent over FY 82 payments of \$34.3 billion and \$14.8 billion respectively. Almost half of the amount of the increase resulted from increases in hospital costs and higher physician fees recognized by the program. Studies discussed in Chapter III of this report indicate that price inflation contributes most to these increases. The remainder of the increases were due to such factors as utilization of more expensive technology in health care delivery, increasing rates of utilization of services, and increases in both the number of aged beneficiaries and the proportion of persons aged 75 or older within the aged population. The latter group requires more medical services and more frequent hospitalization for longer periods of stay.

Inpatient hospital care accounted for 95 percent of all Part A payments. The program also covers convalescent care after a hospital stay of at least 3 days, either by transfer to a skilled nursing facility or through home health services. (Beginning July 1, 1981, a 3-day hospital stay was no longer needed to qualify for home health services under Part A.) Benefit payments for these two levels of extended care services represented 5 percent of total Part A payments.

Medical insurance payments were predominantly for physician and Part B suppliers' services accounting for 74 percent of Part B payments. The next highest reimbursed category was outpatient services (19 percent), followed by inpatient services furnished by radiologists and pathologists (4 percent), group practice prepayment plans (2 percent), and laboratory services (1 percent). A negligible amount was paid under Part B for home health services (0.1 percent) because, since the 3-day qualifying hospital stay was dropped for Part A coverage, most home health services are covered under Part A.

Inpatient Hospital Services

During FY 83, approximately 115 million inpatient hospital days were approved for payment. The aged accounted for 88 percent of the total, while the remaining 12 percent were for the disabled. The rate of covered days of care per 1,000 enrollees was about 38,000 for the aged and 4,700 for the disabled. In FY 83, hospitals were paid \$36.1 billion for Part A benefits, 95 percent of all Part A payments.

Skilled Nursing Facilities Services

During FY 83, 8.8 million days in skilled nursing facilities were approved for payment; 8.5 million were incurred by the aged and 0.3 million by the disabled. This represents an annual rate of 320 covered days per 1,000 aged enrollees and 100 covered days per 1,000 disabled enrollees. Benefits paid totaled approximately \$515 million or 1.4 percent of total Part A payments in FY 83.

Home Health Services

Almost 35 million visits provided by home health agency personnel were approved for payment during FY 83, an average of 1,190 visits per 1,000 aged enrollees and 1,070 per 1,000 disabled enrollees. Home health service benefit payments under both hospital and medical insurance totaled \$1.5 billion for FY 83, representing nearly 3 percent of total Medicare benefit payments. For home health services, physicians are prohibited from certifying the need for such services and establishing a plan of care if they have a significant ownership interest or significant contractual or financial interest in the home health agency.

Physician and Other Part B Supplier Services

For FY 83, medical insurance payments for physicians (excluding inpatient radiology and pathology services) and other Part B suppliers totaled \$12.9 billion, about 74 percent of total Part B payments.

Radiology and Pathology

Payments in FY 83 for inpatient services furnished by radiologists and pathologists amounted to \$611 million, or 3.5 percent of Part B payments.

Other Medical Services and Supplies

For FY 83, approximately \$394 million was paid to group practice prepayment plans, \$3.4 billion for outpatient services, and \$190 million for independent laboratory services.

Telephone Directory Listings Under Medicare

In September, all Medicare Part B contractors were instructed to have their local and toll-free telephone numbers displayed with "Medicare" in the White Pages of the telephone directories which cover their service areas.

Centralization of the Direct Billing and Collection Operation

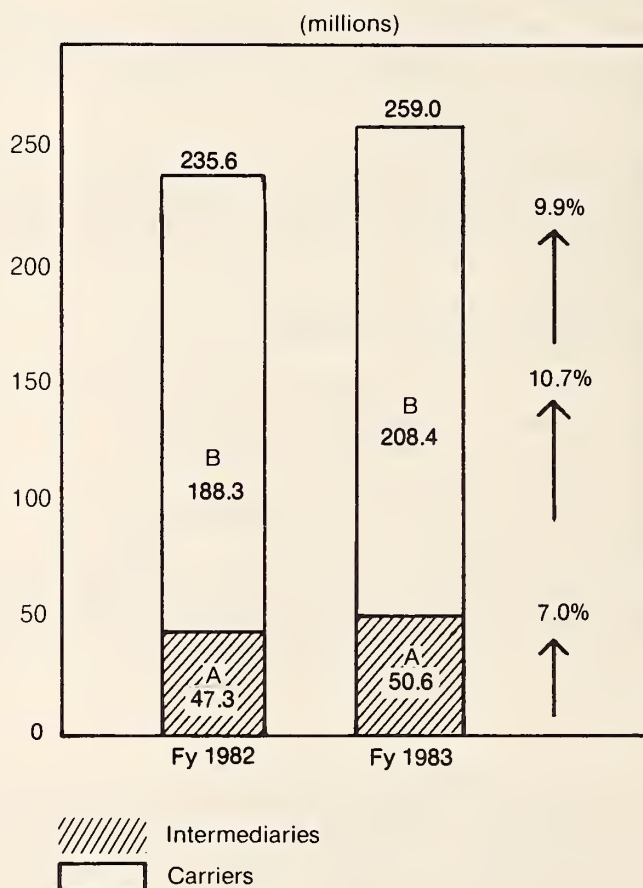
Until September 1982, the Social Security Administration printed and mailed bills from its Baltimore headquarters to approximately 825,000 Medicare beneficiaries who are billed directly for their Medicare premiums. These punch card bills and premium payments were then returned to eight different SSA Program Service Centers for processing.

As of September 1982, this punch card operation was converted to a centralized lockbox operation; that is, all premiums are paid to and processed by a private bank. This approach has several advantages. Beneficiaries are provided a portion of the new bill as a receipt, the bill is easily readable and is processed using automated equipment. In addition, beneficiaries now receive the bills at least 5 days earlier and all funds collected by the lockbox bank are deposited to the Treasury Department within 72 hours. The conversion of the operation to a lockbox bank resulted in yearly savings of about \$1,550,000.

D. CLAIMS PROCESSING PERFORMANCE

Claims receipts--The volume of Medicare claims received continued to increase through FY 83. Contributing to this upward trend were the steady increase in the number of covered beneficiaries, increased utilization of covered services, and the tendency of beneficiaries to submit claims for each bill or service received rather than accumulating them for periodic submittal. Claims received by Part A intermediaries increased to 50.6 million in FY 83, an increase of 7.0 percent over FY 82 experience. Claims received by carriers rose at a rate of 10.7 percent, totaling 208.4 million in FY 83. Overall, the increase in Medicare claims was 9.9 percent.

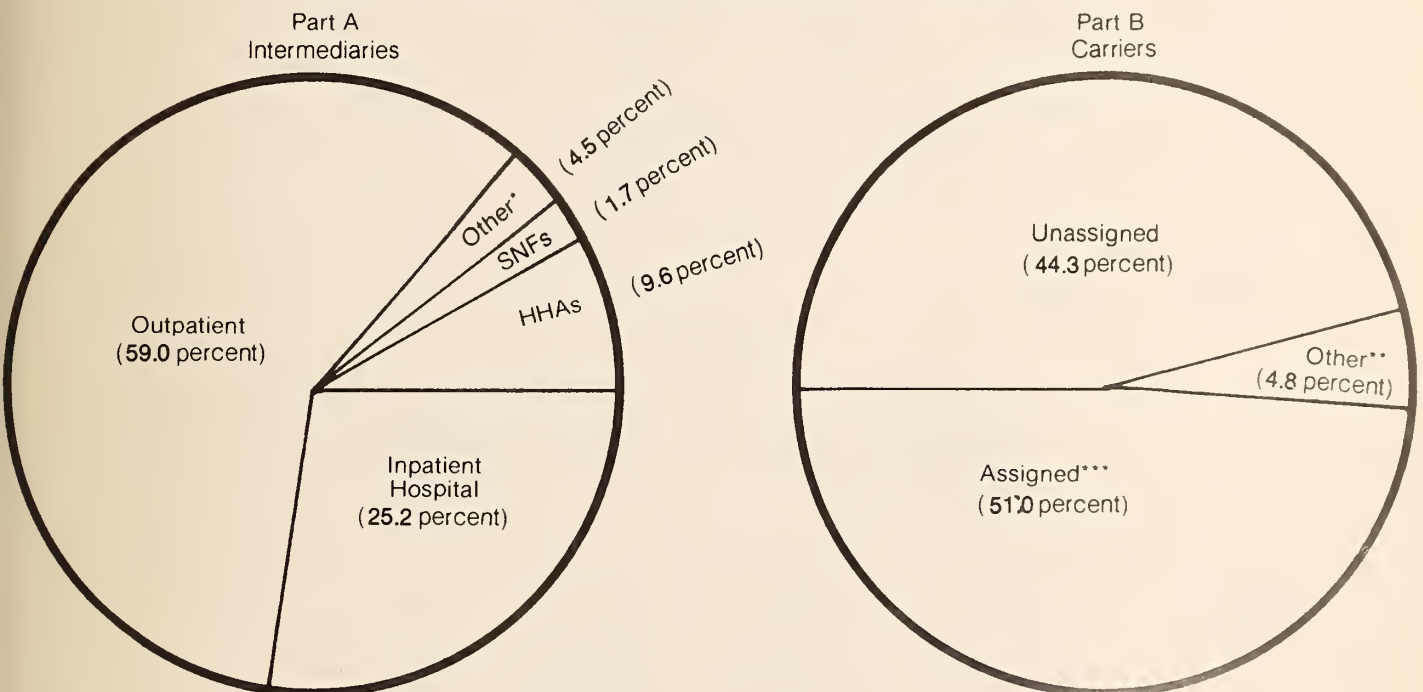
Claims Received by Medicare Contractors



Distribution of Claims - The majority of claims received by intermediaries during FY 83 represented requests for payment for outpatient services provided Medicare beneficiaries. These claims accounted for 59.0 percent of the total received by intermediaries. Inpatient hospital claims accounted for 25.2 percent of the receipts while claims for home health agency and skilled nursing facility services represented 9.6 percent and 1.7 percent, respectively. The remaining 4.5 percent were claims submitted for ancillary and other miscellaneous services payable under Part B.

Claims received by carriers during FY 83 were nearly equally divided between those submitted by physicians and suppliers on assignment (51.0 percent) and the combined total of those submitted unassigned by beneficiaries (44.3 percent) and those submitted by provider-based physicians and group practice prepayment plans (4.8 percent). In comparison to FY 82 experience, the percent of assigned claims to total claims showed a slight increase of 0.9 percentage points.

Distribution of FY 83 Receipts by Type of Claim



* Ancillary and other miscellaneous services payable under Part B.

** Claims for services provided by provider-based physicians and group practice prepayment plans, who do not bill patients directly.

*** This represents the assignment rate measured against all claims. When measured only against claims in which patients are billed directly (i.e., excluding the 4.8 percent of claims for provider-based physician services and group practice prepayment plan services), the assignment rate in FY 83 was 53.9 percent, the figure usually quoted as the Medicare assignment rate. This is a slight increase over FY 82 assignment rate of 52.8 percent.

Claims Processing Timeliness--When compared to FY 82 experience, the timeliness measures of contractor claims processing performance in FY 83 indicated an overall improvement for both Part A intermediaries and Part B carriers. The average processing time for intermediaries decreased from 8.4 days to 7.0 days, and the average monthly percentage of bills pending over 30 days decreased from 13.7 percent to 11.6 percent. Carriers showed a decrease in yearly average claim processing time from 10.5 days to 9.9 days. Over the same time period the average monthly percentage of claims pending over 30 days for carriers decreased from 11.2 percent to 9.9 percent.

Intermediaries

	<u>Contractor Processing Time (Mean Days)</u>		<u>Percent of Claims Pending Over (30 Days)</u>	
<u>Quarter</u>	<u>FY '82</u>	<u>FY '83</u>	<u>FY '82</u>	<u>FY '83</u>
1	8.5	6.9	14.7	12.2
2	9.5	7.5	14.7	10.9
3	8.1	6.6	13.5	10.6
4	7.3	7.0	12.0	12.8
Yearly Average	8.4	7.0	13.7	11.6

Carriers

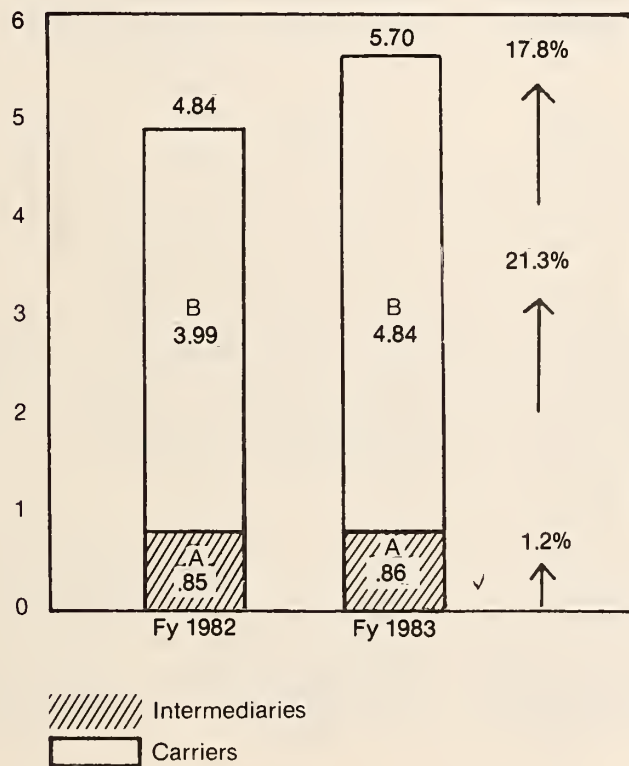
	<u>Contractor Processing Time (Mean Days)</u>		<u>Percent of Claims Pending Over (30 Days)</u>	
<u>Quarter</u>	<u>FY '82</u>	<u>FY ' 83</u>	<u>FY '82</u>	<u>FY '83</u>
1	10.2	9.0	12.9	9.0
2	11.9	10.8	12.0	10.8
3	10.2	9.4	9.0	9.4
4	9.6	10.4	10.8	10.4
Yearly Average	10.5	9.9	11.2	9.9

Claims Pending

Intermediaries experienced an increase in the volume of pending claims in FY 83 compared to FY 82, with a 1.2 percent increase to 856,600 claims. Part B carriers' pending claims in FY 83 showed an increase of 21.3 percent from FY 82, when there were 3.99 million pending claims.

Claims Pending for Medicare Contractors

(millions)



E. CONTRACTOR ADMINISTRATIVE COST EXPERIENCE

Intermediaries

The FY 1983 intermediary workload increased 6.9 percent over FY 1982, whereas the total cost (excluding audit) increased 12.9 percent. Person years for operations (excluding audit) decreased 3.6 percent in 1983 which, in view of the higher workload, resulted in a 10.0 percent increase in productivity per person year.

The unit cost for all operations increased 29 cents, and the unit cost for operations (excluding audit) remained unchanged, thus, the entire increase is attributable to audit costs.

	<u>FY 1982</u>	<u>FY 1983</u>	<u>Net Change Increase (Decrease)</u>	<u>Percent Change Increase (Decrease)</u>
Workload	45,551,680	48,688,877	3,137,197	6.9
Total Cost	\$231,930,888	\$261,824,227	\$29,893,339	12.9
Provider Audit	\$ 69,462,781	\$ 87,993,831	\$18,531,050	26.6
Total Cost (Ex. Audit)	\$162,468,107	\$173,830,396	\$11,362,289	7.0
Unit Cost	\$5.09	\$5.38	\$ 0.29	5.7
Unit Cost (Ex. Audit)	\$3.57	\$3.57	\$ 0.00	0.0

Carriers

The unit cost decreased by 9 cents during FY 1983. This reflects a workload increase of 9.8 percent and total cost increase of 5.9 percent. Contributing to the lower unit cost was the fact that productivity increased 14.2 percent, while the personal service cost per person year increased by 7.9 percent.

	<u>FY 1982</u>	<u>FY 1983</u>	<u>Net Change Increase (Decrease)</u>	<u>Percent Change Increase (Decrease)</u>
Workload	185,769,597	204,048,829	18,279,232	9.8
Total Cost	\$458,819,529	\$485,833,257	\$27,013,728	5.9
Unit Cost	\$2.47	\$2.38	\$(0.09)	(3.6)

F. PROGRAM FUNDING

Under the Social Security Act, the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund are administered by two Boards of Trustees, each comprised of the same three members who serve in an ex officio capacity. The Secretary of the Treasury is designated by law as the managing trustee of both funds. The other members of the Board are the Secretary of Labor and the Secretary of Health and Human Services. The Administrator of the Health Care Financing Administration serves as Secretary of both Boards. The two Trust Funds were established on July 30, 1965, as separate accounts in the U.S. Treasury to hold the amounts accumulated under the respective programs. The Board of Trustees issues annual reports on the status of the two Trust funds.

The primary source of hospital insurance (Part A) financing (92 percent) is contributions, based on earnings, by workers and their employers, and by self-employed individuals. The remaining eight percent is derived from general revenues for certain insured individuals who attained age 65 before 1975, premium payments for voluntarily enrolled individuals, transfers from the Railroad Retirement Board, appropriations for military service credits, Professional Standards Review Organizations, and Maternal and Child Health, and interest on accumulated funds.

Supplementary medical insurance (SMI or Part B) is financed by three sources: (1) premium payments from enrollees, (2) contributions from general revenues, and (3) interest on trust fund accumulation.

When the SMI Trust Fund was initially established in 1966, the Government contribution from general revenues was equal to the premium income collected from beneficiaries under a 50/50 matching formula. Effective in 1973, under a legislative amendment, year-to-year increases in beneficiary premiums were limited to the percent by which general Social Security benefit levels had increased in the preceding year. Since July 1973, the Government contribution has increased significantly. In FY 82, the Government contributed 70.3 percent of program income and the beneficiary contribution was 26.7 percent of program income. The remaining three percent of the income resulted from interest accumulated by the trust fund. The increase in the Government's contribution can be attributed to (1) the 1973 legislative amendment, and (2) the fact that the cost of the Part B program has increased at a rate considerably above the general cost of living adjustment applied to Social Security benefit increases. Some factors contributing to the rise in the cost of the Part B program are (1) inflation of medical prices, (2) utilization of more expensive technology in health care delivery, (3) increasing rates of utilization of services, and (4) increases in both the number of aged beneficiaries and the proportion of persons aged 75 and older within the aged population. Additionally, coverage of the disabled became effective in July 1973 at the same premium rate as for beneficiaries over 65, even though medical care costs for the disabled are greater.

More detailed information about the status of the Hospital Insurance and Supplementary Medical Insurance Trust Funds, showing income, disbursement and future projections are contained in the Annual Reports submitted to the Congress by the Boards of Trustees of the two Funds.

G. CONTRACTOR PERFORMANCE EVALUATION PROGRAM (CPEP)

In FY 83, HCFA evaluated the performance of Medicare contractors by using the Contractor Performance Evaluation Program. In this program, specified criteria are used to measure contractor Part A (hospital insurance) and Part B (medical insurance) performance in the areas of: bill processing (claims processing - Part B), utilization safeguards - Part B only, provider reimbursement (program payment - Part B), beneficiary services, fiscal administration, and general administration. These criteria are applied uniformly to all contractors within each program. Standards for unit cost of bill (claims) processing, timeliness of bill (claim) processing, timeliness of cost report settlements (Part A only), and quality of claims processing (Part B only) were also, established. The process of applying standards and criteria to intermediary performance began on October 1, 1979. Carrier performance initially became subject to the application of standards and criteria on October 1, 1980. Each subsequent year the standards and criteria have been revised and refined to measure contractor performance more accurately.

The CPEP is administered through HCFA's ten regional offices. Throughout the fiscal year, the regional staffs evaluate contractor performance by conducting onsite reviews and analyzing performance data. At the end of the year, Annual Contractor Evaluation Reports (ACERs) are prepared citing CPEP results and are published by the regions for each contractor in their service area.

HCFA uses the results of the application of CPEP criteria and standards to the contractors' performance to identify contractors having deficient performance. When combined with historical perspective, this process has proven to be an effective tool for identifying those contractors exhibiting a pattern of continuing poor performance with little or no apparent improvement. Establishment of performance goals and monitoring systems, and the practice of conducting face-to-face meetings between senior HCFA staff and executives of poor performing contractors, have achieved overall improvements in contractor operations.

The principal objective of the FY 1983 revision process was to adapt the contractor performance evaluation system to the present environment of Medicare administrative budget constraints. Working actively with the Performance Standards and Evaluation Technical Advisory Group (PS&ETAG) and HCFA regional offices, HCFA reached this objective through the process of streamlining. The guiding principles of the streamlining process were articulated as follows:

- o Standards and criteria should be reduced to only those which are truly essential for measuring the contractor's ability to make accurate program payments on a timely basis at the least administrative cost while preserving basic beneficiary services.
- o Standards should be outcome oriented to the extent possible.
- o Performance criteria, as well as the scoring methodology, should create incentives for accurate and cost-effective operations.

The FY 1983 Contractor Performance Evaluation Program (CPEP) clearly reflected the significance of these streamlining principles. The FY 1983 Part A and Part B evaluation programs each consisted of three performance and three statistical standards. The number of performance criteria was reduced by approximately 50 percent for Part A and 60 percent for Part B. Performance elements that evaluated process were eliminated except in cases where standardized process was essential or the process impacted on program dollars: e.g. overpayment recovery activities. Performance elements were added that emphasized the importance of program cost control in evaluating contractors; e.g., standards to assess the quality of Part A utilization determinations, refined Part B medical review process and standards for accurate processing of End Stage Renal Disease (ESRD) claims. In addition, a unified scoring system of performance and statistical standards was developed to replace the previous two-tier system.

The statistical standards revision process was similarly guided by the current Medicare administrative budget environment. Standards measuring the timeliness of bills and claims were relaxed to give contractors greater flexibility in resource utilization. The quality of intermediary cost report settlement, as reflected by Cost Report Evaluation Program (CREP) performance, was substituted for the cost report settlement timeliness standards as a relevant evaluation measure in the current environment. Claims processing quality was measured by an overpayment-deductible error rate and an underpayment error rate based on the Part B Quality Assurance Program. As with the program related standards, the influence of program cost control on these statistical measures was readily apparent.

Continuing the tradition that was created during the initial performance standard developmental process, HCFA and the PS&E TAG worked closely to ensure that streamlining was an analytical process rather than a mere reduction in the number of mandated performance measures. The HCFA-TAG consultation process for FY 1983 featured exchanges of issue papers, several conference calls, two workgroup meetings with the entire TAG, several meetings of the statistical workgroup plus ongoing interaction between HCFA and the co-chairmen via letter and telephone. The issues raised by the advisory group members, as well as their comments on draft standards, stimulated the type of analyses that often led to improved evaluation measures. In addition, HCFA regional office staff participated in the workgroup sessions and the resultant interaction added a new, positive dimension to the overall process. While the rapidly changing Medicare administrative environment occasionally impacted on the totality of the consultation process, HCFA has continued to keep the TAG informed of significant changes to the standards in as timely a manner as conditions have permitted.

CHAPTER II. PROGRAM ADMINISTRATION

A. SUMMARY OF ADMINISTRATIVE STRUCTURE

The overall responsibility for administration of Medicare is vested by law in the Secretary of Health and Human Services. The statute also provides for significant participation in certain areas of administration by private organizations and public agencies.

Within the Department of Health and Human Services, primary responsibility for administering the Medicare program is assigned to the Health Care Financing Administration (HCFA). Special responsibilities in connection with health care standards of Medicare have been assigned to the Public Health Service. The Office of Civil Rights of the Department is responsible for assuring necessary conformance by participating health care facilities with Title VI of the Civil Rights Act of 1964.

Role of the Health Care Financing Administration - The Health Care Financing Administration negotiates and administers agreements with (1) the intermediaries and carriers which perform payment and other program functions, (2) the State agencies which certify health facilities for participation in the program, and (3) hospitals and other institutions which provide services for which the program makes reimbursement. HCFA enrolls Medicare beneficiaries and ensures that a Medicare card is mailed to each entitled beneficiary. It bills and collects premiums from direct-paying beneficiaries and third party payors. It maintains computerized master records which provide current information about beneficiary eligibility, deductible status, and utilization. HCFA also develops reimbursement principles and guidelines, participates with the Public Health Service in the formulation of the conditions of participation, formulates Medicare regulations, develops program policy and procedural instructions, and performs the basic recordkeeping and data processing functions required for administration of the program. It determines and reconciles payment liability of group health plans. Additionally, HCFA assures the quality, appropriateness and necessity of services for program beneficiaries.

Role of the Social Security Administration (SSA) - With the establishment of HCFA on March 8, 1977, responsibility for Medicare activities was transferred from SSA. However, by agreement, SSA continues to perform some functions. Chief among these are: (1) District Office Services - Applicants for Medicare continue to make applications for Medicare coverage, as well as make inquiries and file appeals, to SSA District Offices. SSA District Office staff also respond to inquiries regarding Medicare, process beneficiary appeals, explain Medicare eligibility requirements, make eligibility determinations, obtain required proofs, and issue notice of Medicare eligibility; (2) Computer Support - SSA provides computer resources and operational personnel to process HCFA programs; (3) Appeals Function - Certain appeals functions are handled by SSA. These include beneficiary appeals (Part A) where more than a statutory minimum is at issue.

Role of the Public Health Service - The Department's Public Health Service (PHS) acts as a valuable resource in the professional health aspects of the Medicare program. PHS participates with the Health Care Financing Administration in formulating the conditions of participation for providers of services, provides assistance to the State agencies in carrying out their Medicare responsibilities, supports and evaluates experimental approaches to utilization review, and provides

professional advice on many technical and medical aspects of program administration.

During FY 83, HCFA referred 16 new coverage issues to the PHS, and published 27 instructions based on advice received from the PHS. An additional number of coverage issues were resolved without the need for published instructions.

Role of the Office for Civil Rights - Title VI of the Civil Rights Act of 1964 provides that no institution, agency, or activity receiving Federal financial assistance may engage in discriminatory practice on the basis of race, color, or national origin. Thus, before any hospital, skilled nursing facility or home health agency may be a participating provider under Medicare, their compliance with the provisions of Title VI must be assured. The Office for Civil Rights is responsible for assuring compliance with Title VI.

Role of the State Agencies - The law requires that, wherever possible, the Secretary uses the services of appropriate State or local health agencies or other appropriate State or local agencies in determining whether providers of services and independent laboratories meet the conditions for participation in the Medicare program. All 55 jurisdictions (including the District of Columbia, Puerto Rico, the Virgin Islands, Guam, and American Samoa) have designated agencies -- in most instances State health agencies -- to perform this function.

In carrying out their responsibilities under the health insurance program, the State agencies conduct field surveys of institutions and agencies to determine the extent to which these facilities meet the applicable conditions of participation. They also undertake periodic resurveys of participating facilities to determine whether they continue to meet such conditions and provide consultative services to facilities experiencing difficulties in meeting the participation requirements. The agencies identify non-participating hospitals which can be reimbursed under the program for emergency services, and coordinate activities under the health insurance program with activities conducted under medical assistance programs. The State agencies are reimbursed for the costs of activities they perform in the program, including related costs of administrative overhead and staff.

Role of the Intermediaries - Participating hospitals, skilled nursing facilities, and home health agencies may either receive program reimbursement through a fiscal intermediary or receive payment directly from the Government. Most providers have chosen to deal through intermediaries. Under agreements with the Secretary of Health and Human Services, the intermediary is responsible for determining, within explicit regulations and guidelines, whether services are covered, and the reasonable costs of services provided to beneficiaries, as well as for reimbursing providers for these costs on behalf of the program. In addition, the agreements authorize the intermediary to provide consultative services to providers, to make audits of provider records, and perform related functions. All agreements also require that the intermediary must assist providers in establishing and applying safeguards against the unnecessary use of services covered under the program.

As of September 30, 1983, eight insurers operated as fiscal intermediaries on behalf of over 14,000 participating providers. The insurers include the Blue Cross and Blue Shield Association (with subcontracts to 56 Blue Cross plans) and 6 commercial insurers (Appendix A). Submitting bills directly to HCFA were: 152 hospitals, 35 skilled nursing facilities, 485 home health agencies, 20 outpatient physical therapy providers, 377 Federal hospitals, 6 emergency hospitals, 35 hospitals providing services to migrant farm workers and 6 free-standing end-stage renal disease dialysis facilities. In addition to this regular intermediary workload, HCFA serviced 1,600 other providers involved in program demonstration projects. HCFA also provided accounting and reimbursement services (but not claims processing services) for 34 Kaiser-Permanent facilities nationally.

Role of the Carriers - To make program payments under the medical insurance program, the Secretary is authorized to enter into contracts with organizations already engaged in providing, paying for, or reimbursing the cost of health services under group insurance policies or similar group arrangements in return for premiums or other periodic charges. Applying Federal statutes, regulations and instructions, the selected carriers determine whether services are covered and the amounts to pay physicians and suppliers for services rendered under the program and make payments for such services on behalf of the program. Under the terms of their contracts with the Secretary, they are required to assist in the application of safeguards against the unnecessary utilization of services, and to serve as a channel of communication for information relating to the administration of the program. As of September 30, 1983, there were 26 Blue Shield plans, 11 insurance companies, 1 data processing company, and 0 State agencies operating as carriers (Appendix B).

B. ACHIEVING MORE EFFICIENT INTERMEDIARY AND CARRIER PERFORMANCE

Essentially, beneficiaries and the health community, as well as the public at large, judge the performance of Medicare by the performance of intermediaries and carriers. Contractors' effectiveness in processing claims, in communicating program policies and procedures to the public and in establishing relationships with the health community, shapes the public and professional response to the program.

Within general guidelines issued by the Health Care Financing Administration, the intermediaries and carriers must develop effective administrative mechanisms for achieving required program results. This has led to different patterns in the internal administration and operation of the intermediaries and carriers. Much of the success of Medicare, particularly its acceptance by the health community, is attributable to the opportunities presented by such an administrative pattern. Intermediaries and carriers can develop uniquely responsive mechanisms to meet the variable patterns in the nation's health care system.

Description of Intermediary Claims Process

Basically the Part A intermediary claims process involves (1) determining the amount of program reimbursement due to the provider for covered services furnished Medicare beneficiaries and (2) making periodic payment of those amounts to providers. In the intermediary claims process the provider, rather than the beneficiary, submits the claims. Each claim is a bill of record of services rendered which is accumulated with all other such records from that provider until the end of its accounting period. At that time a final cost settlement is made for all covered services rendered by the provider in that accounting period.

The intermediary claims process for Part A hospital insurance claims is summarized as follows: When a Medicare beneficiary is admitted to a participating hospital or skilled nursing facility, or begins a course of treatment based on a plan of care from a home health agency, the provider sends the intermediary an admission or a start-of-care notice. The intermediary queries the Health Care Financing Administration's central record system for the patient's entitlement and deductible status, and remaining eligibility for benefits. The intermediary then advises the provider of the patient's eligibility for further benefits and his deductible status. Admission and start-of-care notices are sent to the Health Care Financing Administration by teletype or magnetic tape, or by direct magnetic tape to magnetic tape transmission over high-speed wires. Replies are usually sent to the intermediary on the second working day after a request for eligibility information has been made.

During the course of treatment, or after beneficiaries are discharged from the hospital or skilled nursing facility or complete a course of home health treatments, the provider submits claims to the intermediary. These claims are used to determine the level of interim payment due the provider, subject to final settlement at the end of the accounting period. Utilization data are forwarded to the Health Care Financing Administration to update the central records. Consequently, accurate information can be provided when replying to subsequent notices of admission or starts of home health care. As part of the updating process, Explanation of Medicare Benefit notices are sent to the beneficiaries to inform them of (1) services for which the program paid, and (2) the inpatient days or home health visits used in the current benefit period.

Description of Carrier Claims Process - Carriers reimburse reasonable charges on all claims for physicians' services and other covered medical services that are reimbursable on a charge basis. These claims may or may not be accompanied by copies of physicians' or suppliers' bills. If beneficiaries complete the claim form, they attach bills received. Bills are not attached if the claim is completed by a physician or supplier under assignment, or as an assistance to the claimant. Every claim received by the carrier requires two determinations in respect to each distinct service furnished the beneficiary. First, a determination must be made as to whether the service is covered. If the service is covered, a determination must be made as to the reasonable charge for that service. The efficiency of the carrier claims process is, therefore, greatly dependent upon securing detailed itemization of services rendered. Additionally, carriers must maintain accurate and current information concerning independent physician and supplier charge patterns for similar services to other patients in the same locality.

The basic steps in the carrier claims process are briefly summarized as follows: Upon receipt of claims, controls are established to assure proper disposition and to permit location of claims in the event of inquiry. Claims are reviewed for coverage of services and for completeness of information. They are then forwarded for determination of reasonable charges. The bill charges are compared with the customary charges of the physician for such services, and with the prevailing charge established in the locality for similar services. Increasingly, this comparison is accomplished through a computer process in order to handle the volume of claims expeditiously and economically.

It should be noted that each carrier receives claims for payment of medical insurance benefits provided by physicians or suppliers located within its geographic area. This continuity of relationship between the carrier and the physicians and suppliers in a geographical area is essential for the establishment and maintenance of customary and prevailing charge data.

As in the hospital insurance program, HCFA maintains a master eligibility and utilization record of all medical insurance enrollees. As an important step in the claims process, carriers must determine current claimant eligibility for benefits and whether the claimant has met the current year deductible. If the carrier has processed claims earlier in the year, its history file may have information regarding the status of the deductible. If not, the carrier queries the HCFA master record by transmitting essential identifying information and the amount of the reasonable charge. The same transmittal facilities available for intermediaries in Part A are used. HCFA, in updating the master record, responds to the query, generally within 24 hours. HCFA verifies eligibility and identifies the amount of the deductible remaining to be satisfied. The carrier then makes the appropriate payment to the physician or supplier if an assignment has been taken or, if not, to the beneficiary. In assignment cases, the explanation is sent to the physician or supplier with a copy to the beneficiary.

Contractor Performance Evaluation Program (CPEP)

Performance measures mandated by Public Law 95-142 were first applied to intermediaries effective FY 1980 and to carriers for FY 1981. Each subsequent year the performance criteria and statistical standards are revised and refined to measure contractor performance more precisely. In FY 1983, HCFA measured intermediaries in the areas of Bill Processing, Provider Reimbursement, and Contract Management. Carriers were measured in the areas of Claim Processing, Program Payment, Contract Management and quality of claims processing. Both types of contractors were also measured in terms of unit cost of claims processing and timeliness of claims processing. Due to budget limitations the number of measures employed was reduced. The resulting streamlined CPEP focused on product-oriented measures and on those functions which enhance program savings and cost avoidance.

Cost Report Evaluation Program (CREP)

CREP is designed to evaluate the quality of the settlement of Medicare hospital and home health agency (HHA) cost reports. CREP reviews are conducted on an annual cycle from October-September of each year. These reviews are performed on a valid statistical sample which in FY 1983 was drawn from a universe of approximately 6,800 hospitals and 3,100 HHAs. These reviews were the basis for designing corrective action strategies for errors in cost settlements; identifying and recouping overpayments; identifying areas in the regulation, instructions, and policies which require revision or clarifications; issuing an annual analysis report; and assessing regional offices in performance of administering the program.

Carrier Quality Assurance Program

The Health Care Financing Administration also maintains a formal carrier quality assurance program. The primary purpose of the program is to provide a statistically valid and objective procedure for evaluating Part B contractors' performances in the quality of claims processing.

Target Rate Implementation Monitoring (TRIM) Program

In FY 1983, TRIM was designed and implemented to concurrently monitor the quality of base year audits and computations of the target amount per discharge under the Prospective Payment System.

Fiscal Intermediaries determined the target amount per discharge for each hospital before it came under the prospective payment system. The base period costs and resulting target amount per discharge established by the intermediary are not subject to change subsequent to the beginning of the hospital's first cost reporting period under the prospective system, except that correction for mathematical or computational errors will be permitted for a 90-day period following the date the hospital is sent the notification of the determination of these amounts.

The regional offices have the primary responsibility for reviewing, evaluating, and determining the adequacy of intermediary performance. TRIM objectively evaluates and improves intermediary performance by identifying areas for improvement.

Contracting Initiatives and Experiments

Under Section 222 of P.L. 92-603, HCFA was granted experimental authority to test incentive contracting for intermediary and carrier administrative functions. Under an incentive contract, intermediaries and carriers are reimbursed on other than a cost related basis, rather than on actual costs incurred. They are at risk and may suffer monetary damages for failure to meet performance objectives. In addition, certain fixed price contractors also may receive incentive payments if their performance exceeds contractual requirements. As a result of assuming the risk of nonperformance, the intermediary's or carrier's internal management is responsible for improved efficiency and economy in operations. HCFA has taken action in the experimental contracts to assure that a continuing high level of service to Medicare beneficiaries and providers is maintained. In each experimental contract, performance requirements have been introduced which exceed those applied to the incumbent contractors reimbursed on a cost basis.

The use of incentive contracts on an experimental basis, authorized by Congress in 1972, is a departure from the basis statutory authority directing HCFA to reimburse contractors for the necessary and proper cost of administration of their contract duties. The experimental contract utilize selected performance standards and existing quality control and performance review procedures and provide for the assessment of liquidated damages if the contractor fails to meet the standards established. Evaluations are made of actual performance against the standards. They are completed on a quarterly basis by regional office staff.

Maryland, Maine, Illinois, New York - By FY 78, four experimental contracts were awarded. They involved the Maryland, Maine, Illinois, and upstate New York carrier service areas. The first was an annual prospectively negotiated fixed rate experiment with an incumbent carrier. The second, third, and fourth were competitively bid fixed-priced contracts for Part B carrier geographic areas. The experimental contracts have been evaluated to determine the advantage and disadvantage of these forms of contracts. They have concluded that the process of selection and subsequent negotiations of these experimental contracts has demonstrated the willingness of the Blue Cross Plans, the Blue Shield Plans and commercial insurance companies to operate in an incentive/risk environment and use specific standards to measure performance which may result in monetary damages being assessed for poor performance.

Maryland - The Maryland Blue Shield contract was the first incentive-type reimbursement contract between HCFA and one of its Part B contractors. This experimental contract was an annual prospectively negotiated fixed rate experiment. This prospective fixed rate contractual agreement with Maryland Blue Shield followed a general solicitation to all Part B Medicare carriers for participation in a fixed rate experiment. Nineteen carriers responded to the general solicitation. The experimental fixed rate contract with Maryland Blue Shield was for a two-year period (calendar years 1977 and 1978). In the experiment, Maryland Blue Shield realized net earnings in the first year of \$274,161, which included a reduction in payments for failure to satisfy one of the performance requirements in the agreement. The second operational year (calendar 1978) of the contract had a negotiated fixed rate 8.1 percent below that which was negotiated in the first year of the contract. During 1978, the contractor sustained a net loss of \$74,597, thus

realizing a net gain over actual incurred costs of \$199,564, or 2.64 percent, for the two years. As of January 1, 1979, Maryland Blue Shield reverted to a cost contract in accordance with the option contained in the experimental contract.

In 1977, the Union Mutual Life Insurance Company in Maine decided not to renew its Medicare Part B carrier contract but rather, to concentrate its efforts and resources on private business. This decision and the relatively small claims volume for Maine presented an ideal opportunity to test the competitive fixed-price concept in Medicare under the experimental provisions of Section 222 of P.L. 92-603. Through competitive selection, Blue Shield of Massachusetts (BSM) was chosen to replace Union Mutual. BSM contracted with HCFA to process Part B medical insurance claims for fixed-price from December 1977 through September 1980. The contract held BSM to performance standards, including provisions for liquidated damages in the event of substandard performance.

During FY 1979, HCFA and BSM successfully negotiated a one year extension to the existing contract to process the Maine Part B workload for a price of \$2,190,227. On February 6, 1981, HCFA recompeted the Maine Part B contract. Announcement of award occurred on June 1, 1981. The successful offeror was again BSM. The term of the contract was October 1, 1981 - September 30, 1984. During the fall of 1983, HCFA again exercised its option and negotiated a one year extension (October 1, 1984 to September 30, 1985) with BSM. The savings to date from these experimental contracts are \$943,000.

The HCFA experimental fixed-price contract in Illinois was designed to test the effect of merging carrier service areas and the cost benefit effects of price competition in a medium claims volume service area. The service areas involved are Cook County, formerly serviced by the Health Care Service Corporation (HCSC), and the remainder of the State of Illinois, formerly serviced by Continental Casualty (CNA). The operational period of the fixed-price contract was April 1979 to September 1983. The successful offeror for this contract was Electronic Data Systems Federal Corporation (EDSF), an organization that had not been a carrier in the Medicare program but had extensive experience in Medicare data processing. The projected savings to be realized by this experimental contract amounted to \$39,618,000. Some major operational difficulties were experienced during the first year for which liquidated damages were assessable (\$2,037,750 in liquidated damages were assessed through September 30, 1981); however, the contractor then made significant progress in overcoming those difficulties.

A competitive procurement to select a carrier for the State of Illinois through competition was completed in 1983, and a contract was awarded to Health Care Services Corporation on July 15, 1983. EDSF and General American were the unsuccessful competitors. The term of the contract is April 2, 1984 - March 31, 1987 for \$29,200,850 with a projected savings over the term of the contract of \$55,151,000.

In New York, HCFA selected a Part B carrier for the upstate New York area through a competitive process. The experimental contract was intended to test the cost benefit effect and operating efficiencies of merging three carrier service areas in the aggregate medium claims volume service area. The area was previously serviced by Blue Shield of Western New York, Genesee Valley Medical Care, Inc.,

and Metropolitan Life Insurance Company. The successful offeror for this contract was an incumbent carrier, Blue Shield of Western New York (BSWNY). The operational period of this contract was June 1979 to September 1982. The savings realized for this contract were \$15,496,000. Liquidated damages were assessed against this contract in the amount of \$110,816 for performance deficiencies in the period January through June 1980.

The performance difficulties encountered at the beginning of the contract period were corrected, and by the time the contract expired in September 1982, the carrier was among the best performing carriers nationally. Since October 1982, BSWNY has been operating under a cost reimbursement contract with a negotiated ceiling on costs, above which the government will not be responsible.

In FY 80, HCFA negotiated a Part A fixed-price incentive contract with the Blue Cross Association (BCA) and Blue Cross/Blue Shield (BC/BS) of Greater New York (Plan) to consolidate all the Blue Cross Plans in the State of New York. This procurement resulted from an unsolicited proposal submitted by Blue Cross Association and the Plan. Under the contractual arrangement, BCA is the intermediary and Blue Cross and Blue Shield of Greater New York serves as the subcontractor and handles the operational aspects of the arrangement. The outgoing Plans continue to be involved under purchase service agreements for beneficiary and provider services in their localities. The contract, which became operational during FY 81, reduced the number of subcontractors (Blue Cross Plans) within the State from seven to one. The outgoing Blue Cross Plans terminated their operations on a staggered schedule and the central site in Syracuse assumed the entire operation May 1, 1981. The contract extends through April 30, 1984, and provides incentives for excellent performance as well as for the imposition of liquidated damages for less than satisfactory performance. The new subcontractor will process an estimated 12.8 million bills during the term of the contract. The total amount of the operational phase of the contract is \$48,903,000.

The original three year contract was due to end on April 30, 1984, but contained a provision for a negotiated extension. An extension until September 30, 1987 has been negotiated with a projected savings of \$15,204,000.

The first fixed-price competitive bid contract under Part A was to have been awarded for the State of Missouri on July 2, 1979. The term of the contract was to have been January 1, 1980, through December 31, 1982. Court action was initiated against DHHS and on June 29, 1979, the U.S. District Court for the Western District of Missouri rendered a decision which enjoined DHHS from making an award in the procurement. Among other things, the parties initiating the suit contended that the planned experiment violated existing Medicare legislation, which permits participating providers of health care services to nominate their Part A fiscal intermediary. On August 27, 1979, DHHS filed an appeal with the U.S. Court of Appeals for the Eighth Circuit requesting a reversal of the lower court's decision. On June 9, 1980, favorable decisions for the Government were rendered by the Appeals Court in Missouri and subsequently by the District Court after additional litigation. Thereafter, on September 19, 1980, HCFA proceeded with the experiment by updating the Request for Procurement (RFP) and seeking "Best and Final" offers from those organizations which had responded to the original RFP. Following an

evaluation of these "Best and Final" offers, HCFA announced on November 19, 1980, that a contract would be entered into with Blue Cross of St. Louis. The new contract period is from November 10, 1980, through November 30, 1984 and contains provisions for the assessment of liquidated damages in the event of poor performance. The total cost of the contract is \$13,791,100, with a projected savings of \$2 million. An extension has been negotiated until July 1, 1985 at a cost of \$6,185,550 for the one year extension of the operational phase of the contract.

For an experiment to test the potential efficiencies of merging several contractor operations in a multi-State environment and the feasibility of a common claims process for the Medicare Parts A and B programs, an RFP in the Colorado, Utah, and Wyoming service area was released on August 2, 1979. A preproposal conference on the RFP was held on September 12, 1979. On September 14, 1979, the BCBSA, along with BCBSC, Blue Cross and Blue Shield of Wyoming and Blue Shield of Utah, filed a suit with the U.S. District Court for the Western District of Wyoming requesting that the DHHS be enjoined from conducting this experiment. The issues in the litigation were similar to those in the Missouri litigation. On November 1, 1979, the Court enjoined DHHS from awarding a contract under this proposed experiment. On December 31, 1979, DHHS filed an appeal with the U.S. Court of Appeals for the 10th Circuit. The final brief was submitted by DHHS on August 22, 1980. (In a decision rendered November 19, 1981, DHHS (HCFA) won all points.)

While HCFA received a favorable decision from the United States Appellate Court the elapsed time between the receipt of the proposals and the date of the Appellate Court's decision invalidated prior proposals. It was, therefore, necessary for HCFA to reassess the practicability of the planned multi-State experiment. After considering the issues involved, HCFA issued a new RFP for a competitive fixed-price contract with provisions for incentive payments and assessment of liquidated damages. The procurement would be a combined Part A and B experiment for the State of Colorado only.

The RFP to select a single contractor to administer the combined Medicare Part A and Part B programs for the State of Colorado was issued on August 9, 1982.

We received only one proposal. The single offer was one of the incumbent contractors, Blue Cross and Blue Shield of Colorado (BCBSC). Electronic Data Systems Federal (EDSF) was named as subcontractor in the BCBSC proposal. In addition to the primary proposal, BCBSC submitted an alternative proposal, which became the winning bid. Announcement of award occurred on December 10, 1982. Under the alternative proposal, BCBSC proposed that the existing Part A Processing operation system be continued in operation until June 30, 1983. Total costs for the contract was \$31,899,866 with a projected savings of \$4,008,900.

Effective May 2, 1983, providers serviced by Mutual of Omaha and the Aetna Life and Casualty were converted to Part A processing under the existing Medicare Part A system in use by BCBSC. For Part A, all Colorado providers were converted on July 1, 1983, to the EDSF's total Medicare system. All provider reimbursement and cost report settlement processes required in the RFP were unchanged, and the Part B operational date of August 1, 1983 was completed in accordance with RFP requirements.

Other FY 83 Ongoing Performance Improvement Initiatives:

1. Intermediary Systems Testing Project (ISTP)

ISTP is a mechanism designed to evaluate the performance of Part A claims processing systems. It is a tool used to detect contractor systems deficiencies and claims processing weaknesses. The test simulates live processing by providing the contractor with a package of 133 sample claims (bills) covering a wide range of bill processing situations and error conditions. The sample claims are to be processed from the initial query stage to final bill disposition. ISTP contains bills which are used to test the intermediary's ability to make correct entitlement, eligibility, and utilization determinations. The sample bills are processed from the initial query stage to final bill disposition, thus encompassing the following major areas of Part A claims processing:

- a. Query/Query reply
- b. Payment calculation
- c. Notices sent to beneficiary and provider
- d. Payment preparation and disbursement

In FY 1983, tests were conducted at 15 intermediary sites.

2. Carrier Systems Testing Project (CSTP)

CSTP is a mechanism designed to evaluate the performance of Part B claims processing systems. It is a tool used to detect contractor systems deficiencies and claims processing weaknesses. The test simulates live processing by providing the contractor with a package of 167 sample claims covering a wide range of claims processing situations and error conditions. The sample claims are to be processed beginning with their clerical input to the final disposition of the Explanation of Medicare Benefits (EOMB).

CSTP reviews major areas of Part B claims processing such as:

- a. Query/Query reply
- b. Payment calculation
- c. Notices sent to beneficiary
- d. Payment preparation and disbursement

In FY 1983, tests were conducted at 23 carrier sites.

3. Automated Billing

HCFA's efforts to increase the volume of electronic media claims (EMC) submitted to contractors (intermediaries and carriers) increased significantly since July 1982 when national and regional EMC goals were established. The EMC goals were established by individual contractors as a percentage of their total claims volume receipts that they were expected to receive electronically. During FY 1983, a regional office electronic media claims (EMC) workgroup consisting of representatives from each regional office was established for the purpose of concentrating and coordinating HCFA efforts to encourage EMC. The overall EMC effort was successful, as demonstrated by

the fact that the FY 1983 national Part A EMC goal of 27 percent was achieved and that Part B EMC receipts increased 37 percent to reach a national average of 11 percent. The FY 1984 EMC goals are 45 percent for Part A and 17 percent for Part B.

4. Provider Uniform Billing

HCFA is requiring nationwide implementation of HCFA-1450 uniform bill for all inpatient and outpatient Medicare hospital billings by October 1, 1984, the culmination of an effort that began during FY 1983. A standard electronic billing specification using the UB-82 data set has also been developed and published and may be implemented in lieu of the paper form.

5. Beneficiary Toll Free Telephone Service

During FY 83, the Part B carriers received over four and one-half million beneficiary inquiries on toll free lines at an approximate cost of \$2.23 per call or \$.05 per claim processed. Total administrative cost to the program was \$10.8 million. Toll free service is generally perceived by the public as a valuable and tangible indication of the contractors' responsiveness to beneficiary concerns. It also encourages the public to call the contractor about Medicare questions rather than the Social Security district offices.

C. REIMBURSEMENT CONTROLS/POLICY INITIATIVES

The Medicare program presently has two components established by Title XVIII of the Social Security Act. Hospital Insurance (Part A) provides for payment of inpatient services furnished by hospitals and other institutional providers of services on either a "reasonable cost" or, for most hospitals beginning in FY 84, a prospective payment basis. Supplementary Medical Insurance (Part B) provides for reasonable cost reimbursement of outpatient institutional services and payment for services furnished by physicians and other suppliers on a "reasonable charge" basis.

To implement these reimbursement provisions, it is essential that the Medicare program establish principles that ensure the continued delivery of high quality health services to beneficiaries by establishing adequate and timely prospective payments and assuring that unwarranted costs and charges are not paid. In FY 83, several reimbursement policy initiatives were undertaken to continue to meet these objectives.

FY 83 Medicare Reimbursement and Payment Initiatives

Background - Under the original Act, provider reimbursement of reasonable costs included all necessary and proper expenses incurred in the delivery of patient care. It was soon recognized, however, that reimbursement on the basis of incurred costs did not offer sufficient incentives to control the rapid escalation of health care expenditures. The enactment of P.L. 92-603, the Social Security Amendments of 1972, greatly enhanced HCFA's ability to control Medicare costs.

Section 223 of P.L. 92-603 amended the definition of reasonable cost in Section 1861(v)(1) of the Social Security Act to exclude costs determined to be unnecessary in the efficient delivery of needed health services. Congress reasoned that health care institutions, like other enterprises, should face the financial consequences of inefficiency. The Amendments authorized the establishment of prospective limits so that providers could act to control their costs. It was felt that the establishment of prospective limits would reduce provider financial uncertainty by defining limits prior to the onset of the cost reporting period to which they applied.

Regulations implementing Section 223 authorized the establishment of prospective cost limits based on provider classification according to such factors as similarity in size, location, and economic characteristics. The regulations also established the conditions under which providers may be entitled to a change in classification, an exemption from, or an exception to the limits. The statute and regulations also provided for relief by allowing a provider, under certain circumstances, to charge excess costs to the beneficiary.

Although HCFA calculated limits for each type of home health service, the various cost finding methods used by providers made it impractical to apply the limits directly to the per visit cost of individual services. Therefore, HHA cost limits were applied on an aggregate basis. That is, the limits for each type of service were multiplied by the number of visits for that service. The sum of the resulting amounts was then compared to the agency's aggregate allowable Medicare costs. However, mandatory uniform cost finding for HHAs effective October 1, 1980 will eventually permit the direct application of limits for each type of service.

For the HHA limits effective July 1, 1980, HCFA adopted several features common to the hospital and skilled nursing facility methodologies. The revised system is based on an urban/rural classification system with separate categories for hospital-based and freestanding agencies. The new methodology also incorporates the hospital wage index to recognize differences in area wage levels (an HHA specific index is presently not available) and relies on an HHA market basket for inflation adjustments. The level of the limits was established at the 75th percentile by the Omnibus Reconciliation Act of 1981. The limits published in September 1982 incorporated the TEFRA provision requiring that hospital-based agency limits be based on the costs of freestanding agencies. To establish the limits for hospital-based agencies, 13 percent of median hospital-based agency costs was added to the freestanding limit to recognize additional overhead costs allocated to the HHA as the result of the Medicare cost finding methodology.

For the limits effective July 1, 1980, HCFA retained the basic features of the FY 1979 limits. However, a further adjustment was provided to account for additional costs which result from teaching programs but not specifically identified as teaching costs. Also, the proportion of costs subject to adjustment by the wage index was increased to approximate the actual economic environment. Because these improvements enhanced cost homogeneity, the level of the limits was set at 112 percent of the group mean. A mean based threshold avoided the objection to the percentile based limits under which a certain percentage of hospitals in each group was judged inefficient even where actual cost variations were minor. The limits effective July 1, 1981, retained the same methodology used in FY 1980.

Medicare Hospital Reimbursement Reform - On September 3, 1982 P.L. 97-248, the Tax Equity and Fiscal Responsibility Act of 1982, was enacted. Section 101 of that law added section 1886 to the Social Security Act. This new section included a number of provisions restricting the level of Medicare payment for the cost of inpatient hospital services effective with cost reports beginning in FY 83 (on or after October 1, 1982).

First, it provides for extension of the section 223 hospital cost limits, which applied only to inpatient general routine operating costs, to total operating costs of inpatient hospital services, including routine operating costs, ancillary service operating costs, and intensive care unit operating costs. The limits are to be applied on an average cost per discharge basis, rather than on a per diem basis, and adjusted for each hospital based on the Medicare case-mix experience for that hospital. Historical cost report data used in computing the limits are to be updated using a factor based on a combination of actual historical rates of increase and the hospital wage and price index, plus one percentage point. No hospital's limit will be lower than its allowable operating costs per discharge for inpatient services during its last cost-reporting period immediately preceding the first cost-reporting period subject to the new limits. Non-SMSA hospitals which were operating with less than 50 beds on September 3, 1982 are exempt from the limits. The Secretary may provide for other exemptions, exceptions and adjustments to the limits. (By regulation long-term hospitals with lengths of stay in excess of 25 days, psychiatric hospitals, Christian science sanatoria, children's hospitals and all hospital subproviders are excluded from the cost per discharge limits.)

Secondly, it provides for a new 3-year limitation on payment for hospital cost that is separate from the type of limit established under section 223. This new limitation establishes a target percentage rate of increase in hospital inpatient operating cost per discharge. The target rate is based on the percentage rate of increase in the hospital wage and price index, plus one percentage point. In the first year subject to the ceiling (that is, cost-reporting periods beginning on or after October 1, 1982), a target amount will be established for each hospital equal to the hospital's allowable operating cost per discharge for the immediately preceding 12-month cost-reporting period, increased by the target percentage. For subsequent years, a hospital's inpatient operating cost per discharge target amount would be computed by increasing the previous year's target amount by the current year's target percentage. The legislation provides for incentive payments to hospitals that keep their cost increases below the target amounts, as well as penalties for hospitals that incur costs greater than the target amounts. A hospital that incurs allowable cost per discharge below its target amount will be paid its costs plus the lesser of 5 percent of the target amount or 50 percent of the difference between its actual costs and the target amount. A hospital that incurs allowable costs per discharge above its target amount will be reimbursed the target amount plus 25 percent of its costs in excess of the target amount for its first two cost-reporting periods subject to the ceiling. None of the excess cost will be reimbursed in the third cost-reporting period subject to the ceiling. In no event may payment under the ceiling provision exceed the amount payable under the new cost limits. The Secretary will also provide certain exemptions, exceptions and adjustments considered appropriate for this part of section 101. (By regulation the rate of increase ceiling is applicable to all hospitals, except for any new providers or risk-basis HMOs that have been granted a specific exemption by HCFA.)

Additionally, section 101(b) of P.L. 97-248 required the Secretary to develop in consultation with the Senate Committee on Finance and the House of Representatives Committee on Ways and Means, a legislative proposal for Medicare payment to hospitals, skilled nursing facilities, and to the extent feasible, other providers, on a prospective basis. The Secretary submitted, on December 27, 1982 the Department's proposal in a report to Congress titled Hospital Prospective Payment for Medicare. A proposal on prospective payment for skilled nursing facilities will be issued separately.

Medicare Hospital Prospective Payment System - On April 20, 1983, P.L. 98-21, the Social Security Amendments of 1983 was enacted. Title VI of P.L. 98-21 provides for Medicare payment for hospital inpatient services under a prospective payment system, rather than on a reasonable cost basis. Interim final regulations implementing Title VI of P.L. 98-21 were published September 1, 1983 and instructions on how to determine and make payments under the new system were released during the period May through August 1983.

The new program required a complete change in the way hospitals subject to it are reimbursed. Essentially, Medicare payment will be made at a predetermined, specific rate for each discharge. All discharges are classified according to a list of diagnosis related groups (DRGs). This list contains 468 specific categories. The prospective payment rate will not include capital related costs (e.g., depreciation, taxes, rent, etc.) direct medical education and kidney acquisition costs which will continue to be reimbursed under a reasonable cost based system.

The statute provides for a 3-year transition period during which a declining portion of the total prospective payment will be based on hospitals' historical costs in a given base year and a gradually increasing portion will be based on a regional and/or national Federal rate per discharge. Beginning with the fourth year and continuing thereafter (i.e., cost reporting periods beginning on or after October 1, 1986), Medicare payment for hospital inpatient services will be determined fully under a national DRG payment methodology.

The statute excludes several types of hospitals and hospital units from the prospective payment system. These include psychiatric, long-term, children's, and rehabilitation hospitals as well as psychiatric and rehabilitation units operating as distinct parts of acute care hospitals. Hospitals located outside the 50 States and the District of Columbia are also excluded. The excluded facilities and units will continue to be reimbursed on the basis of reasonable costs subject to the target rate of increase limits. In addition to the above categorical exclusions from prospective payment, the statute provides for other special exclusions, such as hospitals that are covered under approved State reimbursement control systems.

The Federal payment rates are determined based on the mean urban or rural standard amount per discharge. During the transition period separate urban and rural Federal payment amounts will be computed for each of the nine census divisions in the country as well as the nation as a whole, making 20 payment amounts. For payment of a particular case, this amount is then adjusted to account for area differences in hospital wages and multiplied by the relative weight of the DRG to which the patient is assigned (DRG weight) is a measure which reflects the relative resources consumed in treating a patient assigned to the DRG. The standard amounts per discharge will be updated annually. For FY 84 and FY 85, the prospective payment system must be "budget neutral." That is, payments may not be greater than, nor less than, the payments that would have been paid under the TEFRA total cost limits. Beginning with FY 86, the Secretary will determine the update factor taking into consideration recommendations made by The Prospective Payment Assessment Commission, a panel of independent experts appointed by the Director of the Office of Technology Assessment.

Additional payments will be made to hospitals for discharges meeting specified criteria as "outliers." Outliers are cases that have an extremely long length of stay or unusually high cost when compared to most discharges classified in the same DRG. Additional payments will also be made for indirect costs of approved graduate medical education programs.

Beneficiaries may be charged only for deductibles, coinsurance amounts, and non-covered services (e.g., phone, television, etc.). They may not be charged for differences between the hospital's cost of providing covered care and the Medicare payment amount.

Under the prospective payment system, payment will be made to the hospital on a per discharge basis. Therefore, hospitals may have incentives to increase admissions or reduce services. To safeguard against such practices, the statute requires the establishment of a monitoring system to review admission practices and quality of care. If an abuse of the prospective payment system is discovered (e.g., unnecessary multiple admissions of the same beneficiary or inappropriate medical practices), payment may be partially or totally denied to the hospital.

In addition to the general Medicare demonstration authority, P.L. 98-21 requires that certain research projects be conducted related to Medicare program costs and payment methods. The statute also requires a large number of reports to the Congress on specified areas of study, including recommendations for legislative changes. Final regulations and further clarification and updating of rates was scheduled to be completed in FY 84.

Treatment of Cost of Uncompensated Services Furnished in Fulfillment of a Hill-Burton Free Care Obligation - Under the Hill-Burton legislation amending the Public Health Service Act, medical care facilities applying for grants, loans, and loan subsidizes are required to assure that they will make available "a reasonable volume of uncompensated services to persons unable to pay" for them. Under program rules each facility that received Hill-Burton financing is obligated to furnish annually, for a twenty-year period, a certain volume of uncompensated services. In accordance with section 106 of TEFRA, during FY 82, HCFA developed a regulation to state explicitly that, with certain exceptions, Medicare will not share in the costs of uncompensated services furnished by a provider in fulfillment of a Hill-Burton free care obligation. This regulation was issued on October 1, 1982, as a final with a comment period.

Reimbursement For Hospice Care - Section 122 of the Tax Equity and Fiscal Responsibility Act authorized coverage for hospice care services effective November 1983. Hospices provide care to terminally ill individuals. The final regulations implementing this provision outline eligibility requirements, establish conditions of participation, define covered services and implement a prospective payment system for hospice care. With the exception of payment for physician services, the prospective payment system provides reimbursement at one of four predetermined rates for each day of hospice care, depending on the level of care furnished to the individual. Physician services will be reimbursed separately to the hospices on a fee-for service basis. The Medicare hospice benefit is a Part A benefit, and will end on September 30, 1986, under current legislation.

The methodology was substantially revised for the hospital limits effective July 1, 1979. Costs not reflective of relative efficiency of operation, such as capital, malpractice insurance, and medical education expenses, were excluded in deriving and applying the limits. All urban hospitals were then classified into four bed size groups without any distinction for economic environment. Rural hospitals were categorized into three bed size groups in the same way. The portion of cost attributable to wages was adjusted for differences in area wage levels by an index developed from hospital wages paid within the locale. Hospital costs were previously adjusted for inflation using a "market basket" of goods and services hospitals typically purchased in furnishing routine care. Prior to adoption of the technique, inflation adjustments were based on actuarial estimates of cost increases. Additionally, HCFA included an adjustment to increase the limits for hospitals located in States furnishing less than the national average days of care per 1,000 Medicare beneficiaries.

Purchased Management and Administrative Support Services

Under Medicare principles of reimbursement in 42 CFR 405.451, providers of services may not be reimbursed for unreasonable costs. Reasonable costs are limited to necessary and proper costs prudently incurred by a provider in furnishing services under title XVIII and related to the care of beneficiaries. As a result of questions regarding the reasonable cost of management and administrative support services purchased by providers, HCFA issued manual instructions in March 1982 which provide guidelines for applying the principle of reasonable cost to the cost of these purchased services.

In November 1982 the instructions were revised to clarify that they were not intended to dissuade providers from seeking or utilizing alternatives to in-house services. The new instructions emphasized that HCFA encourages providers to always consider the most appropriate means for obtaining services needed for the ongoing rendition of patient care. Therefore a provider is required to initially determine whether the services it needs can be obtained more effectively using in-house staff or through outside contractors, and to select the most prudent and cost-conscious method.

Reimbursement for Assistants at Surgery (Section 113)

The provision prohibits reasonable charge reimbursement for an assistant at surgery in hospitals where an approved training program exists in the specialty and a qualified staff physician is available to provide the service, except when: (1) the surgery is performed by a team of physicians needed to perform complex medical procedures; (2) the patient has multiple conditions which require the presence of, and active care by, a physician of another specialty during surgery; and (3) exceptional medical circumstances exist. Interim final regulations implementing this provision were issued October 1, 1982.

Elimination of Medicare Indirect Subsidy for Private Rooms

Section 111 of P.L. 97-248 specifies that the Secretary shall not allow as a reasonable cost the estimated amount by which costs for nonmedically necessary private rooms used by Medicare beneficiaries exceeds the costs which would have been incurred for semi-private accommodations. On February 10, 1983, HCFA published a final rule implementing section 111 for cost reporting periods beginning on or after October 1, 1982. Prior to this change in policy, Medicare had been sharing in the cost of nonmedically necessary private rooms for Medicare beneficiaries based on reimbursement for inpatient general routine services on an average cost per diem, including the costs and days of private room accommodations.

Revision of Hospital and Skilled Nursing Facility Cost Reports

During FY 83 the Hospital and Hospital Health Care Complex Cost Report, was revised to implement the provisions of TEFRA, for cost reporting periods beginning on or after October 1, 1982 and before October 1, 1983.

HHA and SNF Cost Limits

The Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) made changes in the SNF and HHA cost limits programs. For cost reporting periods beginning on or after October 1, 1982, separate limits for hospital-based HHAs and SNFs were not permitted. Limits were to be based on the costs of freestanding providers. An add on to the freestanding limits was permitted to recognize higher costs of hospital-based providers resulting either from differences in the case mix of patients treated or from Medicare cost apportionment rules. Limits implementing the TEFRA changes were published in September 1982.

1. Reasonable Cost Limits - Skilled Nursing Facilities

The SNF routine cost limits are very similar in design to those for hospital routine operating costs. The limits are derived from reported inpatient routine services costs of comparable facilities. Comparability is achieved by classifying SNFs according to location (urban or rural) and status as either a freestanding or hospital-based agency.

The SNF limits resemble the 223 hospital limits in other respects as well. Capital related costs are excluded in deriving and applying the limits. The remaining costs are adjusted for inflation using a market basket index based on cost of goods and services which SNFs typically purchase. Differences in routine service costs resulting from differences in prevailing area wage levels are recognized using the same wage index incorporated in the hospital limits. Hospital wage data are used because of the lack of quality wage data suitable for indexing specific to nursing facilities and the similarity of the hospital and SNF labor markets. The level of the limits is also established using a mean based criterion which, effective October 1, 1979, the limit was 115 percent of average group costs. A revised set of limits incorporating several refinements in the initial schedule and setting the level and 112 percent of group mean cost was published in the Federal Register on September 4, 1980 and became effective October 1, 1980. The limits contained no changes in methodology. The notice implementing the TEFRA provision for a single set of limits was published on September 29, 1982. However, section 605 of the 1983 Social Security amendments delayed imposition of the single SNF limits until October 1983.

2. Reasonable Cost Limits - Home Health Agencies

Section 223 limits for home health agency (HHA) costs were first established effective July 1, 1979. These initial limits were based on a classification system which only distinguished between urban and rural providers. They were set at the 80th percentile of per visit costs, derived from the per visit cost of agencies for each of six Medicare covered services: skilled nursing care, physical therapy, speech pathology, occupational therapy, medical social services, and services of home health aides. Cost data were obtained from the Medicare fiscal intermediaries. Inflation adjustments were based on actuarial estimates of increases in interim payments for home health services and a formula for voluntary price restraint in the health care sector established by the Council on Wage and Price Stability.

Elimination of Inpatient Routine Nursing Salary Cost Differential

Section 103 of P.L. 97-248, the Tax Equity and Fiscal Responsibility Act of 1982, eliminated the inpatient routine nursing salary cost differential as an element of reimbursable cost under Medicare for hospitals and skilled nursing care facilities (SNFs). Prior to this legislative change, the Medicare rules for calculating reimbursable costs to these providers included this inpatient routine nursing salary cost differential because it was presumed that patients age 65 and over required more nursing services than the general patient population. The differential, which was also applied to maternity and pediatric patients, was not an add-on to the total routine nursing salary costs incurred by a provider, but rather it was a reallocation of the actual routine nursing salary costs between aged, pediatric, and maternity patients and all other classes of patients.

The provisions of section 103 of P. L. 97-248 were implemented by the October 1, 1982 publication in the Federal Register of a final rule with comment period (47 FR 43618). This amendment was effective for cost reporting periods ending after September 30, 1982.

Elimination of Duplicate Overhead Payment for Outpatient Services (Section 104)

The provision requires the Secretary to issue regulations to eliminate the duplicate payment of overhead expenses from the recognized charges of a physician who performs services in hospital outpatient departments. Interim final regulations implementing this provision were issued on October 1, 1982.

Radiologist/Pathologist (Section 112)

The provision eliminates the 100 percent reimbursement rate previously applicable to inpatient radiology and pathology services. Medicare will pay for such services on the same basis as for other physicians' services, i.e., 80 percent of the reasonable charge after the Part B deductible has been met. Instructions to implement this provision were issued effective for services furnished on or after October 1, 1982.

Cost to Related Organizations - When services, facilities and supplies are furnished to a provider by organizations related to that provider by common ownership or control, the costs may be claimed by the provider cost to the related organization (not to exceed the price of comparable services, facilities, or supplies that could be purchased elsewhere).

Several administrative and judicial disputes resulted from certain ambiguities of this manual section. Therefore, we developed a manual revision to clarify several provisions of this broad principle. Specifically, we (1) provided more realistic and definitive examples of common ownership and control; (2) specified how the costs of a related supplying organization are determined; and (3) clarified the exception to the basic principle by providing examples of criteria for each exception. The manual revision was issued in December 1982.

Reasonable Charge Reimbursement Initiatives

It is common practice for physicians to bill their patients for laboratory tests which have not been performed in their own offices or under their personal supervision but which are acquired for their patients from independent laboratories. In these instances, the physician forwards the specimen to the outside laboratory which, in turn, bills the physician directly for the services performed. As a rule, independent laboratories use lower price schedules when they bill physicians for test than they charge to the general public for similar services. These lower prices to physicians often reflect volume discounts and lower laboratory billing costs resulting from periodic billings.

In recent years, evidence accumulated by the General Accounting Office (GAO), the Congress and the Department has indicated that there are frequently substantial markups on bills submitted by physicians for these services. To help deal with this problem, the Congress enacted Section 918 of P.L. 96-499, the Omnibus Reconciliation Act of 1980, which precludes Medicare reimbursement of such markups.

The initial instructions to implement the new statutory provision were issued to the Medicare carriers in March 1981. A final regulation implementing the provision was published in the Federal Register on August 24, 1981. The new rule provides that: (1) If a bill submitted by a physician indicates that a particular laboratory service was performed by (a) that physician, (b) another physician sharing the practice, or (c) an individual under the physician's supervision, the reimbursement allowed will be based on the reasonable charge for that service. (2) If a physician bills for a laboratory procedure that was performed by an independent clinical laboratory and identifies the laboratory and the amount charged for that service, payment will be based on the lower of the actual charge or by the physician or the laboratory's reasonable charge for the physician. In either case, the physician is also allowed a nominal amount for collection and handling of the specimen if he or she bills for such services. (3) If the physician does not indicate that he or she performed the test, and does not identify both the laboratory and the amount charged for the test, payment is to be based on the lowest amount which the Medicare carrier estimates the test could have been obtained from a laboratory serving the physicians's locality. A nominal specimen collection and handling fee will be paid to the physician only if the physician's bill indicates that the test was performed by an independent laboratory and not by the physician or personnel under his or her supervision.

Another significant change in reasonable charge reimbursement was also made when Section 946 of P.L. 96-499 was implemented. Before enactment of that provision, the Medicare carriers determined reasonable charges for covered services on the basis of the customary and prevailing charge screens in effect at the time the carriers received the claims. However, in March 1981 Section 946, required that reasonable charges must be determined on the basis of the charge screens in effect at the time the services are furnished. The only exception to this rule is that the carriers will not go back further than one year to determine reasonable charges for claims filed after long delays. The final regulation with a comment period implementing this provision was published in the Federal Register on December 31, 1981.

Other Policy Initiatives/Issues Pending at the End of FY 1983

1. Ambulance Services - A final regulation was published in the Federal Register with an effective date of October 18, 1982, that expanded the ambulance service benefit. Coverage was extended to include round-trip transportation of hospital and skilled nursing facility inpatients to other facilities, including such nonhospital facilities as clinics or therapy centers, to obtain medically necessary diagnostic or therapeutic services not available in the originating facility. The regulation recognized developments in medical care practice and health care planning which have made it necessary to provide round-trip transportation for hospital and skilled nursing facility inpatients to other facilities to obtain services. It provided for round-trip transportation of a hospital or skilled nursing facility inpatient to the nearest appropriate treatment facility to obtain medically necessary diagnostic or therapeutic services. The regulation also specified that, in the case of a beneficiary who is being transported to a hospital to become an inpatient, the availability of a physician or physician specialist capable of providing the necessary treatment required by the beneficiary's condition is a factor in determining whether the hospital has appropriate facilities to care for the beneficiary.
2. Oxygen Therapy in the Home - A notice published in the Federal Register on December 14, 1979, contained proposed policies and guidelines that Medicare Part B contractors would apply, where necessary, to claims for oxygen used in the home. The objective was to assure that uniform criteria are applied by contractors in determining whether a valid medical need for oxygen exists so that the home use of oxygen can be paid for by the program. The guidelines proposed medical conditions for which oxygen therapy is appropriate when used by the home patient and also proposed what would be acceptable medical evidence of the need for oxygen. This evidence would include a physician's prescription with specified information and blood gas study reports. The notice also contained a list of questions about different medical aspects of the proposed guidelines in order to obtain as complete a report as possible from the medical community. Criteria and guidelines in this area are being reviewed within the Department and had not been released by September 30, 1983.
3. Exclusion of Heart Transplantation Procedures from Medicare Coverage HCFA discontinued Medicare coverage of heart transplantation procedures effective June 13, 1980. The policy, announced in a HCFA Ruling published in the Federal Register on August 6, 1980, rescinded an earlier interim decision of November 2, 1979 that had authorized coverage for heart transplantation procedures only at Stanford University Medical Center. The Ruling authorized payment for heart transplantation and associated medical treatment at Stanford University Medical Center and at the University of Arizona Medical Center performed on or before June 12, 1980, or for candidates accepted on or before June 12, 1980. It excluded other heart transplantation coverage pending the results of further study.

The Ruling further announced that HCFA, in close cooperation with the Public Health Service, National Center for Health Care Technology, would conduct a broad study of all aspects of Medicare coverage of heart transplants, including social, economic, and scientific issues. The study will also examine the impact of a coverage decision on beneficiaries, the Medicare program, and competing health care providers, and will include patient care costs for a limited number of Medicare beneficiaries accepted for transplantation at appropriate institutions.

The study will consist of two parts. Institutions that agree to participate in Part I will make available data concerning heart transplants performed during the study period, as well as during the most recent five year period. In Part II, a qualified research organization will be selected to develop, evaluate and analyze a wide range of data furnished by institutions participating in the study and from other sources, and will forecast possible scientific, medical, economic and social issues that could affect reimbursement and influence Medicare coverage policy.

When the study results have been analyzed, HCFA intends to publish a proposed decision on Medicare coverage of heart transplants.

The National Heart Transplantation Study

HCFA is sponsoring a broad study of all aspects of Medicare coverage of heart transplants, including social, economic, and scientific issues. This study consists of two parts--a demonstration and a research study. Under the demonstration, HCFA agreed to pay for 15 transplants during the period September 1982-April 1984. During FY 1983, 14 heart transplants were performed.

Under the research part, HCFA awarded the Battelle Human Affairs Research Centers a contract to conduct a study of "The Social and Economic Consequences of Heart Transplantation." The study is attempting to estimate the future need for heart transplants, assess the costs of such transplants, and seek to identify the social, legal, and ethical issues related to heart transplantation.

The study is expected to be completed by the end of August 1984. When the study results have been analyzed, HCFA intends to review its present policy on coverage of heart transplants in the light of the information the study provides.

4. Coverage Decision Procedures - HCFA develops national Medicare coverage policy concerning whether or not health care items and services are medically "reasonable and necessary." The Medicare law prohibits payment for items or services which are not reasonable and necessary for diagnosis or treatment.

A Physicians Panel, comprised of all HCFA physicians and dentists, as well as physicians representing the Public Health Service (PHS), met regularly to discuss and recommend action on new coverage issues before HCFA. During FY 83, HCFA referred 16 new coverage issues to the PHS, and published 27 instructions on coverage issues based on advice received from the PHS.

5. Prohibition Against Payment for Less than Effective Drugs - On June 5, 1980, HCFA published in the Federal Register a proposed rule to prohibit the payment for certain drugs under the Medicare and Medicaid programs. The rule would bar the expenditure of Federal funds under the two programs for drugs determined by the Food and Drug Administration (FDA) to be not effective for any indicated use, and prohibit reimbursement for drugs with certain exceptions that have not been approved by the FDA for sale in interstate commerce. A number of comments were received in response to the proposed rule but before a final regulation could be prepared based on comment analysis, this policy initiative was superseded by enactment of Section 2103 of the Omnibus Budget Reconciliation Act of 1981 (P.L. 97-35). Effective October 1, 1981, this provision prohibited Medicare Part B payment and Medicaid payment for prescribed drugs for which the Secretary has issued a Notice of an Opportunity for a Hearing (NOOH) on a proposed order to withdraw the drug from the market because the FDA has determined that the drug is less than effective for all indicated uses and for which the Secretary has not determined there is a compelling justification for its medical need. This will include any other drug product that is identical, similar or related. Interim final regulations with a comment period implementing this new provision was published in the Federal Register on October 1, 1981. Procedure instructions were issued to Medicare carriers and Medicaid State agencies, containing a list of drug products and known related products lacking substantial evidence of effectiveness and subject to an NOOH.

6. Waiver of Liability--Erroneous Placement in an Inappropriately Certified Bed of a Participating Hospital or SNF

HCFA issued final administrative instructions in February 1983 to implement section 956 of the Omnibus Reconciliation Act of 1980 (P.L. 96-499, the legislation that amended section 1879 of the Act).

The new legislation was enacted to remedy the situation where a beneficiary who otherwise qualifies for Medicare coverage is precluded from program payment solely because he or she received services in a part of a hospital or SNF not qualified to provide the appropriate level of care required by Medicare. Payment under the amended section 1879 is limited to cases in which the inappropriate placement was the result of unintentional, inadvertent, or erroneous action by the provider of services, acting in good faith based on the advice of a utilization review committee physician, Professional Standards Review Organization or fiscal intermediary, or was the result of a clearly erroneous administrative decision by the provider of services.

7. Provider Payment Appeals

On May 23, 1983, HCFA published a final regulation amending the procedures providers follow to bypass a hearing by the Provider Reimbursement Review Board and obtain judicial review. The changes clarify policy not included specifically in the previous regulation text, and were made in response to comments received on the final regulations published in the Federal Register on July 22, 1982, implementing section 955 of P.L. 96-499, the Omnibus Reconciliation Act of 1980. The law applies when the Board determines that

it does not have the authority to decide the point at issue. The Board may determine that it does not have the authority, either on its own motion or upon the request of a provider. In that circumstance, a provider that has the right to obtain a hearing by the Board may bypass the hearing and obtain judicial review of any action of the fiscal intermediary that involves a question of law or regulations relevant to matters in controversy.

On September 1, 1983, HCFA published an interim final regulation with comment period to implement section 602(h) of P. L. 98-21, the Social Security Amendments of 1983. The law provides for Provider Reimbursement Review Board and judicial review of hospital dissatisfaction concerning payment for inpatient hospital services under the DRG prospective payment system. The appeals procedures provided hospitals receiving prospective payment is basically the same as for all providers, permitting review in all cases except for items necessary to maintain budget neutrality and to avoid adversely affecting the establishment of the diagnosis related groups (DRGs), the methodology for the classification of discharges within the DRGs, and the appropriate weighting of each DRG. The regulation implements the law which also expands the judicial review venue provisions by providing a third permissible venue in the case of an action brought jointly by several providers--the judicial district in which the greatest number of providers in the group appeal is located.

The regulation also affords a PPS provider the right to challenge an initial or revised DRG assignment.

8. Medicare as Secondary Payer--In April, 1983, final regulations were issued to implement statutory amendments designed to yield significant cost savings by making Medicare secondary payer for the following services:
 - o Services for which payment has been made or can reasonably be expected to be made under automobile medical or no fault insurance, or any liability insurance. (Section 953 of the Omnibus Reconciliation Act of 1980.)
 - o Services reimbursable under an employer group health plan and furnished to ESRD beneficiaries during a specified period up to 12 months. (Section 2146 of the Omnibus Budget Reconciliation Act of 1981.)
 - o Services reimbursable under an employer group health plan furnished to employed individuals and their spouses age 65 - 69. (Section 116 of the Tax Equity and Fiscal Responsibility Act of 1982.)

Manual instructions for implementing the provisions were issued to contractors and providers in May, 1983.

9. Guidelines for Base Year Audits Under the Medicare Prospective Payment System for Inpatient Hospital Services

The "Guidelines" provided instructions for the fiscal intermediaries to help them expeditiously complete their base year audits on a timely basis preparatory to setting the target rate amount for Inpatient Hospital Services under the Prospective Payment System to be implemented in FY 1984. These instructions included the following areas:

- a) Audit Activity Planning--Development of Inventory of Hospitals to be audited and the resource management necessary to accomplish the audits in the short period of time required.
- b) PreAudit Review--Expanded preaudit review to adequately enable the intermediary to develop the scope of work necessary to determine each hospital's target amount during the review of the base period cost report.
- c) Audit Performance Requirements--Instructions as to HCFA's expectations on the quality of the work to be performed.

10. End Stage Renal Disease (ESRD) Audit Program

HCFA developed two audit programs to audit a sample of independent and hospital based ESRD facilities and their related organizations to determine these facilities' statistical and cost information reported on their most recently filed cost reports presented fairly the facilities costs in conformity with the reporting instructions. The accumulated audit data was used specifically for the following purposes:

- a) To determine if the new cost reporting forms and instructions were being completed properly and if any clarification to these forms or instructions was required.
- b) To establish a statistically valid data base for adjudicating exception requests.
- c) To determine if the composite rate should be updated. (The composite rate reimbursement system is a prospective, incentive system for the payment of outpatient maintenance dialysis services furnished to Medicare beneficiaries).
- d) To document the staffing patterns of renal facilities.
- e) To ascertain the accuracy of the costs allocated to the facility and to identify costs to or from related parties.
- f) To verify that independent facilities are being reimbursed a reasonable cost for supplies and equipment they furnish to Home Dialysis Patients (42 CFR 405.544(b)).

11. Return on Equity - Reimbursement under Medicare includes an allowance for a reasonable return on equity capital invested and used in the provision of patient care. Effective for cost-reporting periods beginning on or after April 20, 1983, the rate of return on equity for inpatient hospital services in proprietary hospitals was reduced from one and one-half times the average of the rates of interest on special issues of public debt obligations issued to the Federal Hospital Insurance Trust Fund to one times that basis. The higher rate, however, will continue to be paid for noninpatient hospital services and for services in other types of providers.
12. Temporary Delay in Periodic Interim Payments

The passage of TEFRA (P.L. 97-248), section 120 provided for the temporary delay in periodic interim payments (PIP) due during the last 3 weeks of September of both 1983 and 1984, to the following October. A general notice was issued in the Federal Register May 27, 1983.

D. IMPROVING UTILIZATION SAFEGUARDS

One of the most critical areas of the Medicare program activity is to establish safeguards against improper and excessive utilization of health care services. A part of the rapidly increasing costs of Medicare continues to be attributable to the furnishing of medical services which are not medically necessary by reference to generally accepted medical practice norms, or which are medically inappropriate, particularly in terms of location of care. Most overutilization does not represent any criminal intent to defraud the Medicare program. Usually they represent "decisions of opportunity," i.e., when a service opportunity is presented which is reimbursable by an external party and there is a lack of rigorous definition about the nature of the service or the reimbursement rules for that service, there is an incentive to render the service with a high degree of expectation that it will be reimbursed. The delivery of medical care is particularly subject to this incentive because the necessity and appropriateness of such services are often judgmental matters. Additionally, some medical practices which tend to induce overutilization have become traditional in the American health care delivery system.

Under the Part A hospital insurance program, one of the most obvious examples of this is unnecessary occupancy of expensive inpatient facilities, when health services at that level of care are not required. An admission to a hospital for services which could be given in a skilled nursing or intermediate care facility or on an outpatient basis, with equal medical effectiveness, is a particularly striking example of such a situation; i.e., a Friday admission to a hospital whose costs are inappropriately generated where extended stays in a facility beyond the patient's medical need for that facility's level of care created a far higher care cost than should be incurred by either the patient or the insurer.

In FY 1978, HCFA began a major consumer information campaign to encourage all Americans to seek a second opinion before undergoing non-emergency surgery. The campaign was directed toward the general public. Publicity to promote the program included radio and T.V. spots, articles distributed to major publications, and cooperation with insurance companies. Much of the publicity was directed in promoting the Hotline number (800-638-6833). In FY 1983 eight million brochures entitled "Thinking of Having Surgery? Think About Getting a Second Opinion" were distributed.

In the medical insurance program, excessive or unnecessary utilization often occurs because the common charge structure for medical services, whether in an outpatient hospital setting or in respect to services furnished by private physicians, is generally that fee is charged for each visit. Under such a system, program reimbursement can be substantially increased solely as a result of an increased number of visits. That increase in number of visits may or may not represent a proportionate increase in either the quantity or quality of medical services rendered. Thus, patients may initiate physician or outpatient visits after their medical needs have been met. Additionally, physicians and outpatient clinics may invite or allow more patient visits than are required for the patient's medical management or which customary practice would ordinarily dictate.

The program approached its responsibilities in the area of utilization safeguards in a number of ways. The structure of the program itself provides some fundamental controls on general utilization. There are benefit limitations on the number of days of care in hospitals and extended care facilities and for home health visits. These limits are intended to assure coverage for the vast majority of medical situations that require these levels of service and yet provide upper limits beyond which program payment would not be made. The program prescribes deductible and coinsurance amounts which may serve as a safeguard against the initiation of unnecessary services because they require patients to share the cost of services and, thus, provide some motivation for them not to seek services unnecessarily or prolong services beyond their medical needs. Particularly significant are the program requirements that, for services to be reimbursable, they must be furnished on a physician's order or under the direction of a physician, and the physician must certify that they are medically necessary. With regard to home health services, a physician is prohibited from certifying the need for such services, or establishing the plan of care, if he or she has a significant ownership interest or significant financial or contractual relationship with the home health agency. Additionally, for inpatient services to be reimbursable, a Professional Standards Review Organization (PSRO), if there is one in the area, must certify that they are medically necessary. Beginning in FY 1984, Medical Review Authority of PSROs under Medicare will have been superseded as Statewide Utilization and Quality Control Peer Review Organizations (PROs) when established.

During FY 83, HCFA continued to refine the prepayment screens which carriers utilize to identify situations of potential overutilization or variations from medical necessity norms.

A particularly important screen, utilized by many Part B carriers, permits the prompt identification of individual physicians whose total bills for Medicare patients in given periods significantly exceed what would normally be expected in ordinary practice. Investigation of physicians identified by means of such a screen can disclose instances of overutilization or cases in which the State or local medical society or even cases of deliberate fraud in which prosecution would be appropriate. The increasing awareness that cases involving possible excessive rates of payment are being investigated constitutes a significant deterrent to overutilization.

Other types of screens which are being increasingly used by carriers provide for the identification of (1) physician-patient contacts which appear abnormally frequent for a particular diagnostic category or therapeutic procedure, (2) potential markup situations where physicians include an added charge for services actually provided by an independent laboratory, or (3) situations in which a physician begins charging separately for component services which had previously been rendered as a combination of package service with a single charge. Carriers are increasingly incorporating such screens into their electronic data processing systems.

It is necessary to recognize that in many instances variations from usual patterns are justified by the facts of an individual case. The important thing, however, is that the Medicare claims review process must be able to identify significant variations so that further review can be undertaken in instances of possible excessive or improper utilization.

HCFA is also continuing its efforts to assure that Medicare payment is only made for items and services which are medically necessary and of acceptable professional quality. This activity takes a variety of forms. First, PSROs and the successor PROs have stringent quality review requirements, and set objectives to be met. These objectives, which must demonstrate impact, range from reducing the risk of mortality to reducing avoidable postoperative infections. Additionally, HCFA continues to identify individual items, services, and procedures which are of questionable value. When HCFA obtains medical evidence that an item, service, or procedure is not safe and effective or that it is experimental, it discontinues payment for it. HCFA conducts these activities with the support of the Public Health Service and in collaboration with national medical and medical specialty societies.

Another dimension of the medical necessity issue relates to determinations as to whether items or services provided to a beneficiary in a specific case are medically necessary. In recent years, criteria have been developed to assist Medicare intermediaries make these determinations. This is a very sensitive area, of course, since such determinations may directly challenge the medical judgement of the physician who ordered or rendered the services. Because this is such a sensitive area, review criteria are developed by physicians, and denials are only made on the basis of a physician's professional judgment. The PSRO program, established in 1972, provides for organizations to develop and apply medical necessity criteria to services rendered in hospitals. PSROs will be superseded by PROs by November 15, 1984.

The inducements to the provision of services beyond medical need are considerable. These inducements range from pressure put on physicians by patients who are familiar with popularized diagnostic and therapeutic procedures and exotic new technologies, to the increasing concern by physicians over potential malpractice suits for failure to provide the entire gamut of diagnostic and therapeutic procedures to every patient. The latter leads to what has been called "defensive medicine." Other inducements are the use of expensive new equipment beyond medical justification in order to amortize the high cost of such equipment and, for some, sheer profit maximation, the additional service, even though unnecessary, does not harm the patient medically or financially, since he or she "has insurance."

In dealing with these problems, HCFA works closely with professional organizations to assure that services are provided and reviewed in accordance with the best professional judgment.

E. QUALITY AND APPROPRIATENESS OF CARE

A major goal of the Medicare program is to assure that its beneficiaries receive appropriate health care services. This is assured by requiring that those facilities caring for Medicare beneficiaries are structurally safe, clean, properly staffed, and provide needed services and that the actual care delivered to beneficiaries meets accepted professional standards. In addition to assuring the quality of services received, HCFA must make sure that services are necessary and performed at the most economical level consistent with good care. These efforts ensure a high quality of care for beneficiaries while simultaneously constraining health care costs.

Standards and Certification

In accordance with the Social Security Act, any facility providing health care services to Medicare beneficiaries must meet certain health and safety standards before it is eligible to receive reimbursement from Medicare. In order to ensure that these standards are met, HCFA provides for periodic survey of each facility. These surveys are conducted by each of the States under contract with the Department. In the case of hospitals, however, the law allows the privately-run Joint Commission on Accreditation of Hospitals (JCAH) and American Osteopathic Association's (AOA) standards and surveys to be considered as having met the Federal government's requirements. Therefore, States only survey those hospitals not accredited by JCAH or AOA and will, on a sample basis, conduct surveys on JCAH and AOA hospitals in order to validate that the surveys conducted by these associations continue to meet Medicare requirements.

Generally, the Federal Standards and Certification program is responsible for establishing and updating Federal health care standards, developing State survey procedures, and monitoring surveys and standards enforcement. During FY 83, program emphasis was placed on (1) upgrading standards affecting the quality of services, (2) developing more efficient and effective survey procedures, (3) reducing regulatory burdens and eliminating duplicative requirements to lessen unnecessary expenses imposed by certain standards. Discussion of major FY 83 activities includes.

1. Conditions of Participation

Conditions of participation establish the requirements for life safety, medical care, nursing care, and physical and social environment that facilities must satisfy to participate in Medicare. During FY 83 two major conditions targeted for regulatory review were:

- o Hospital Conditions of Participation - A notice of proposed rulemaking (NPRM) was published in the Federal Register on January 4, 1983. This proposed rule is part of the Department's regulatory relief efforts and is designed to reduce Federal requirements, simplify and clarify regulations and provide maximum flexibility in administration while protecting patient health and safety. There were over 36,300 letters of comments received on the NPRM. These comments are being evaluated in the development of a final regulation.

- o Skilled Nursing Facility/Intermediate Care Facility (SNF/ICF) Conditions of Participation - A proposal to revise the SNF regulations in FY 82 resulted in wide public protest. As a result, Congress imposed a moratorium on further revisions of SNF and ICF regulations in TEFRA. On expiration of the moratorium, HCFA and Congress reached an agreement to conduct a study through the auspices of the Institute of Medicine, National Academy of Sciences, to analyze a wide range of long-term care issues. Any future changes in SNF/ICF regulations will not take place until the study has been completed.

2. Survey and Certification Procedures (Subpart S)

Survey and certification procedures for Medicare and Medicaid were developed at the time these programs became law. The survey process is an effort to apply the standards and conditions of participation for the Medicare program. Since development of these procedures, some elements have been found to be either unnecessary, or duplicative. In order to address these concerns, this process is also undergoing major review.

In the spring of FY 82 HCFA proposed a series of revisions to the public survey and certification process. The major issues addressed for revision were identified during hearings held in the spring of 1980. These revisions include: (1) provisions mandated by 1980 and 1981 Omnibus Reconciliation Acts; (2) the elimination of nonproductive requirements; (3) consolidation of Medicare and Medicaid certification rules; and (4) elimination of unnecessary differences between Medicare and Medicaid requirements. Revisions to the process are still under review.

3. Professional Standards Review Organizations (PSROs)

In 1972, Congress enacted legislation calling for the establishment of PSROs to ensure that the health care services provided to Medicare and Medicaid beneficiaries are: (1) of a quality that meets professionally recognized standards of care, (2) medically necessary, and (3) appropriately provided in the most economical setting. PSROs are comprised of practicing physicians who engage in various activities associated with the review of care in a given locality. The law provides that PSROs are responsible for the reviews of health care services delivered in hospitals and long-term care facilities.

As a result of the Omnibus Budget Reconciliation Act of 1981, PSROs are required to review only those health services provided to Medicare patients but are no longer required to perform Medicaid reviews, effective October 1, 1981. State Medicaid agencies now have two options: (1) contracting with PSROs for the continued performance of medical or utilization review functions and therefore be deemed to meet the Utilization Control (UC) requirements for those services and providers that the PSRO reviews, or, (2) States may assume direct responsibility for assuring the UC required by the Title XIX of the Social Security Act. Any agreements entered into with a PSRO prior to October 1, 1981 will continue to exist until the next renewal date of the agreement or in accordance with instructions in the existing grant. By November 15, 1984, Medical Review Authority under Medicare will become the responsibility of Utilization and Quality Control Peer Review Organizations (PROs) pursuant to the Peer Review Improvement Act of 1982. As contracts are entered into establishing PROs in each State, PSRO grants will be terminated.

4. Voluntary Second Surgical Opinion Program

In FY 78, HCFA began a major information campaign to encourage consumers to seek a second opinion before undergoing nonemergency surgery. The campaign was particularly directed to Medicare and Medicaid beneficiaries. The campaign is premised on the patient's right to know the benefits and risks of the recommended surgery and any alternatives to that surgery. HCFA's second surgical opinion program centers around the major efforts:

- a national second opinion referral system
- a public information campaign

In FY 83, nearly eight million brochures entitled "Thinking of Having Surgery? Think About Getting a Second Opinion" were distributed to welfare offices, SSA district offices, consumer and professional groups, and individuals throughout the United States. Public service announcements promoting the second opinion program and publicizing the national toll-free number (800-638-6833) were distributed to 730 television stations and over 6,000 radio stations.

Patients wishing second opinions can contact local referral centers or call the national toll-free number to obtain the name and telephone number of their local referral center. Approximately 65,000 calls have been made to the national "hotline" since the inception of the program in October 1979.

F. REPORT ON MEDICARE VALIDATION SURVEYS OF HOSPITALS
ACCREDITED BY THE JOINT COMMISSION ON ACCREDITATION OF
HOSPITALS (JCAH)

A. Introduction

The purpose of the validation program is to determine the effectiveness of the JCAH accreditation process in providing reasonable assurance that hospitals comply with the intent of the Medicare Conditions of Participation. Each year, a statistical sample of the approximately 5,100 JCAH accredited hospitals is selected for validation surveys. Under contract with the Secretary, State agencies (SAs) conducted 54 validation surveys during this report period (FY 83).

B. Statutory Background

Section 1865 of the Social Security Act provides that JCAH accredited hospitals are "deemed" to meet the requirements of the conditions of participation in the Medicare program, except for utilization review or other standards the Secretary promulgates that are higher than JCAH standards. Thus, JCAH accredited hospitals are not subject to annual SA surveys to assess compliance with the conditions of participation.

Subsection 1864(c) of the Act authorizes the Secretary to enter into an agreement with any State to survey hospitals accredited by JCAH on a selective sample basis or in response to substantial allegations of significant deficiencies which would adversely affect the health and safety of patients.

C. Validation and Allegation Process

The Health Care Financing Administration (HCFA) selects a statistical sample of accredited hospitals for validation surveys from scheduled JCAH accreditation surveys. The random selection reflects our urban-rural mix of hospitals, and our range of different sizes of hospitals. This permits us to apply our findings to the universe of JCAH hospitals. SAs survey these hospitals using the Medicare Conditions of Participation. If significant deficiencies are found that could affect the health and safety of patients, the hospital is placed under SA surveillance until the deficiencies are corrected. The hospital is no longer deemed to meet the Medicare Conditions of Participation and the SA monitors the correction of any deficiency as if the hospital were unaccredited.

D. Accreditation Process

The purpose of a JCAH accreditation survey is to assess the extent of a hospital's compliance with the JCAH standards. After the completion of the on-site survey JCAH makes an accreditation decision. Prior to January 1, 1982, the maximum period of JCAH accreditation was 2 years, which was given to hospitals fully meeting JCAH standards. A hospital found to be in substantial compliance with JCAH standards, although demonstrating certain shortcomings, received a 1 year accreditation. On January 1, 1982, JCAH discontinued both 1 and 2 year accreditations, by changing its accreditation

program to a 3 year accreditation with a "contingency" procedure. An accreditation with a contingency stipulates that the accreditation will be withdrawn if the hospital fails to correct the specified deficiencies in the time provided in the notice to the hospital. A contingency may require a focused on-site resurvey which is analogous to a Medicare followup resurvey as they both assess correction in the identified deficiencies. Under JCAH's new accreditation program, a hospital may receive a 3-year accreditation without a contingency; receive a 3-year accreditation with a contingency; or in cases where a hospital fails to achieve substantial overall compliance it would lose its accreditation.

When JCAH increased its accreditation cycle to 3 years, it further strengthened existing monitoring mechanisms to include periodic self-survey reports and/or focused onsite surveyor revisits.

In this report period JCAH performed 1,843 surveys. Thirty-six percent (655 of 1,843) received 3 year accreditations without contingencies, 23 percent (430 of 1,843) received accreditations requiring written contingency reports, 25 percent (406 of 1,843) received accreditations requiring contingency onsite visits and 13 percent (234 of 1,843) received contingencies requiring both written reports and onsite visits. Three percent (56 of 1,843) were not accredited. Sixty-one percent of all JCAH hospitals surveyed received contingencies (23 percent + 25 percent + 13 percent) as compared to 54 percent of the validated hospitals.

In addition to the 54 validation surveys, the SAs also performed 4 full surveys in hospitals that JCAH had performed onsite resurveys, as they had been accredited with contingencies. We added focused onsite resurveys to our study of validated hospitals to be able to examine the JCAH monitoring process. The Medicare surveyors had no knowledge of the nature of the contingencies, providing an opportunity for unbiased comparison.

E. Significant Findings of FY 1983

During FY 83, all 54 of the JCAH validation hospitals were successful in maintaining their accreditation and continuing participation in the Medicare program. Although JCAH and Medicare each found deficiencies, neither program determined that these were situations that posed immediate threats to the health and safety of patients. We have compared deficiencies identified by Medicare surveyors to deficiencies identified by JCAH to assess the comparability of the two survey processes. Fifty-four percent (29 of 54) of validated hospitals were given contingency accreditations. Eighty-six percent (25 of 29) of these deficiencies were also identified by Medicare.

Our analysis was conducted in the two discrete areas: Life Safety Code and general health and safety requirements.

1. Life Safety Code (LSC)

The LSC of the National Fire Protection Association is a consensus standard of requirements, adopted by Federal regulations, that provide a reasonable level of safety from fire and other emergencies. During this report period, 85 percent (46 of 54) of validated hospitals were in compliance with LSC (See Table 1). This is a 13 percent improvement compared to the prior report period in which 72 percent of validated hospitals were in compliance with LSC. For all hospitals validated prior to this report period, 45 percent (315 of 702) were in compliance with LSC. This overall improvement can be attributed to the continued effectiveness of JCAH surveyors in assessing compliance with the LSC and to Medicare's adoption of the Fire Safety Evaluation System (FSES) for validation surveys.

The FSES was developed by the National Bureau of Standards and is a method for assessing compliance with the LSC. The FSES permits a facility to employ alternative measures for meeting LSC requirements while ensuring an equal degree of fire safety.

Medicare recommended in 1980 that JCAH surveyors receive additional training in surveying for smoke barriers. These construction requirements are important because the smoke barriers limit the spread of smoke and toxic gases. Inhalation of these gases is the most frequent cause of death in fires. In this report period, JCAH surveyors found a greater number of smoke barrier deficiencies than did HCFA surveyors, indicating the benefit of the additional training.

However, Medicare surveyors found a greater number of deficiencies related to doors. Patient room doors must conform to the LSC, i.e., be constructed of at least 1 3/4 inch solid wood, not have louvers, not be held open, and not have vision panels without wire glass and metal framing. Hazardous area doors must have door closers. If these hazardous area doors are held open they must be held open by electro-magnetic devices that close doors automatically when activated by fire alarm or smoke detector. The need for additional JCAH surveyor training in evaluating doors and Medicare surveyor training in evaluating smoke barriers is indicated by these findings.

2. General Health and Safety

During this report period, 89 percent (48 of 54) of JCAH accredited hospitals receiving validation surveys were found in compliance by Medicare with general health and safety conditions (See Table 1, Page 54). This is a 10 percent improvement compared with the percentage in compliance (79 percent) in the previous report period.

Within the general health and safety conditions for validated hospitals, the nursing condition is most frequently found out of compliance (See Table 2, Page 54). These findings are consistent with current and prior report periods for both accredited and unaccredited hospitals. Historically, noncompliance with the nursing condition is more frequently associated with hospitals with a small number of beds. All the validated hospitals that were out of compliance with the nursing condition in this report period have a bed-size ranging from 25 to 57. The same problem exists in small, rural unaccredited hospitals.

Each hospital that was found out of compliance with the nursing condition had inadequate numbers of professional nursing staff. Each hospital submitted a plan of correction stating that they already have or will employ more registered nurse staff.

JCAH accepts accreditation by the College of American Pathologists (CAP), an independent accrediting body, in lieu of its own surveys. All validated hospitals that had CAP accredited laboratories were found in compliance by Medicare surveyors. JCAH directly surveyed laboratories in 39 percent (21 of 54) of the validated hospital surveys. Eight-one percent (17 of 21) of the laboratory surveys had similar significant findings by both JCAH and Medicare surveyors. Only 4 percent (2 of 54) were found out of compliance with the laboratory condition. In both hospitals Medicare surveyors identified significant deficiencies in the quality control standard.

3. JCAH Focused Resurvey Findings

The JCAH contingency procedure provided us with a new opportunity to review its monitoring process. HCFA performed full surveys on four hospitals that JCAH accredited with a contingency. The contingency required a JCAH resurvey focused on the area of concern. Although the numbers are small we are encouraged by the similarity of findings. Three of the four hospitals HCFA surveyed had findings similar to the JCAH findings. The Medicare surveyors had no knowledge of the contingencies and found the same deficiencies in: post-anesthesia notes, medical staff review, and LSC. In the hospital for which Medicare and JCAH had different findings, JCAH identified deficiencies in their respiratory care standard, an area for which Medicare has no condition of participation.

4. Substantial Allegation Findings

An accredited hospital is also subject to a SA survey when a complaint alleged that significant deficiencies threaten the health and safety of patients. Surveys made in response to a complaint cover only the conditions related to the complaint. If a significant deficiency is found in this partial survey, then the SA performs a full survey. As with a validation survey, if the SA discovers

significant deficiencies, the hospital continues to be subject to surveillance by the SA (as if it were an unaccredited hospital) until the deficiencies are corrected.

For this report period, 199 hospitals received complaint investigations of which only 14 percent (27 of 199) were found out of compliance with one or more conditions. This is the same percentage found out of compliance as in the last reporting period. Only 1 percent (2 of 199) of these hospitals were found out of compliance with the LSC. Over the previous 4 report periods, an average of 7 percent of these hospitals had LSC deficiencies. This decrease parallels the improvement in validation findings.

Nine percent (17 of 199) of these hospitals were out of compliance with nursing, which is also consistent with previous reporting periods. For all other general health and safety conditions, the rate of noncompliance ranged from 0 percent to 4 percent found out of compliance.

F. Conclusion

Considering both validation surveys and complaint investigations, we found that only 15 percent of all hospitals surveyed were placed under SA surveillance, as compared with 20 percent for the prior report period (FY 82-83), and 35 percent for the previous report period. This continued decrease demonstrates increased equivalency between the JCAH and Medicare survey processes. Except for LSC and nursing conditions, both validation surveys and substantial allegation investigations found all other conditions out of compliance in less than 3 percent of hospitals surveyed.

Accredited hospitals have few problems meeting HCFA standards. Indeed, in many areas, JCAH standards exceed HCFA's requirements.

JCAH has substantially strengthened its capabilities to both evaluate and enforce the LSC requirements. LSC compliance is the same percentage compliance as the percentage of compliance with general health and safety requirements. This is the first time since the validation program was implemented that LSC compliance has been only 4 percent less than general health and safety compliance. Validation surveys for the current report period show that 15 percent of the validated hospitals were out of compliance with LSC. This is 38 percent below the average of the previous 6 report periods, indicating continued improvement in JCAH's ability to survey for these requirements.

Although this is a significant decrease in the number of hospitals found out of compliance with the LSC, JCAH surveyors should continue to receive additional training in some aspects of the LSC. We recommend that JCAH conduct training in patient room and hazardous area door requirements. As demonstrated by validation survey findings regarding smoke barriers, training improves JCAH's ability to survey adequately for this type of requirement.

It is through JCAH and HCFA survey efforts that health care facilities continue to improve. The validation program is a check and a healthy stimulus for both JCAH and the SAs. Without the basis for exchange and comparison of results, both programs would suffer. As long as the standards and program management of both agencies continue to develop and improve, the objectives and intent of both organizations will benefit.

The hospital validation program and the JCAH accreditation program are operating successfully. By monitoring both programs closely, HCFA is alert to any significant changes, and takes immediate corrective actions if problems are identified.

TABLE 1

Validation Surveys

Accredited Hospitals Found In Compliance By Medicare State Survey Agencies

		Previous Report Period FYs 1981 & 1982		Current Report Period FY 1983		Percent Increase Compliance
		<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>	
General Health & Safety	In Compliance Total Surveys	<u>60</u> 76	<u>79</u>	<u>48</u> 54	<u>89</u>	10.0
Life Safety Code	In Compliance Total Surveys	55 76	72	46 54	85	13.0

TABLE 2

Validation Surveys Compared To All Unaccredited Medicare Surveys

Compliance With Nursing Conditions

		Previous Report Period FYs 1981 & 1982				Current Report Period FY 1983			
		<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
Nursing	In Compliance	71	93	1468	96	44	81	990	95
	Total Surveys	76		1521		54		1045	

G. INCREASING HMO ENROLLMENT BY MEDICARE BENEFICIARIES

Health Maintenance Organizations (HMOs) are continuing to increase in number as an alternative to traditional forms of health care delivery. An HMO is an organization which provides its members comprehensive health services, without regard to frequency or extent of services, in return for a predetermined, fixed premium paid by its members. Under traditional methods of health care delivery, an individual buys health insurance from one organization, but has services provided by other individuals and institutions, each of whom bills separately. An HMO, by contrast, is both a health care insurer and a health care provider, with members receiving covered services through the HMO. Because the amount its members pay for the cost of care is fixed in advance, there is great incentive for HMOs to reduce the cost of care. They strive to reduce costs by emphasizing preventive care and health education, by providing only medically necessary care, and by using ambulatory care rather than more expensive inpatient hospital and other institutional care whenever possible.

In the early years of the Medicare program, HMOs and other prepayment plans could be directly reimbursed by Medicare on a capitation basis for only certain Medicare Part B services. But Congress recognized that the HMO's emphasis on keeping down health care costs could produce significant savings for Medicare. Therefore, in 1972, Congress authorized the Medicare program to enter into contracts with HMOs allowing them to be reimbursed on a capitation basis for all covered services under Parts A and B of Medicare furnished to beneficiaries who enrolled in HMOs. Member beneficiaries pay a premium which covers Medicare deductible and coinsurance amounts.

During FY 83, the number of contracting HMOs went from 63 to 75. Medicare membership in HMOs increased from 127,606 to 192,830, an increase of 51 percent.

During 1983, the Health Care Financing Administration continued its emphasis on beneficiary enrollment in HMOs. There were 3.2 million beneficiaries living in HMO service areas who were notified by mail of the availability of HMO services. Medicare enrollment in HMOs is expected to continue to increase substantially.

H. PAYMENTS TO HEALTH MAINTENANCE ORGANIZATIONS AND COMPETITIVE MEDICAL PLANS (Section 114)

Current Law: Health maintenance organizations (HMOs) are reimbursed by Medicare for services covered under both Parts A and B, pursuant to Section 1876 of the Social Security Act. Section 1876 defines an HMO as a legal entity which generally meets the definition in Title XIII of the Public Health Service Act, and which makes Medicare covered services available in a geographic area on a prepayment basis.

Under Section 1876, HMOs receive interim monthly capitation payments based on either cost or risk contracts. An HMO is eligible to enter into a risk-sharing contract if it has at least 25,000 members and has served as the primary source of health care for at least 8,000 persons in the two years immediately preceding the contract, or serves non-urban areas with current enrollments of not less than 5,000 members and which has served as the primary source of health care for at least 1,500 people in the 3 years immediately preceding the contract.

Under risk contracts, reimbursement is based on a comparison of the HMO's costs with its Adjusted Average Per Capita Cost (AAPCC), which is the average cost of providing services to Medicare beneficiaries in the same geographic area as the HMO but who are not enrolled, and having the same characteristics as the enrolled population. If the risk-based HMO's costs are less than the AAPCC, it shares the "savings" with the Medicare program. The organization may receive savings of up to 10 percent of the AAPCC. HMOs are not required to provide additional services with their savings.

TEFRA Modification: In 1982, Section 1876 was significantly changed. The old risk contract option was replaced by prospective reimbursement under risk sharing contracts with HMOs and other eligible organizations at a rate equal to 95 percent of the AAPCC. In addition, a cost contract option remained.

Organizations eligible to enter into contracts are Federally-qualified HMOs or organizations which provide specified health services, receive fixed and periodic payments on behalf of enrollees, provide physician services through staff physicians or physicians under contract, assume financial risk on a prospective basis, and meet financial viability standards. The organization must have at least 5,000 members, although this limitation may be waived for plans in non-urban areas. The organization must provide all Medicare services and the Secretary must approve any required additional services. The organization must also have arrangements for an ongoing quality assurance program, in accordance with regulations to be established by the Secretary.

An annual open enrollment period of at least 30 days is required. Plans must generally accept beneficiaries in order of application up to capacity. A beneficiary may disenroll on a monthly basis with one month's notice. A plan may not disenroll or refuse to reenroll a beneficiary because of health status or services required. Combined Medicare and Medicaid enrollment in the HMO cannot exceed 50 percent of the total enrollment, except under certain circumstances. The Secretary may establish standards for consumer information to be supplied to eligible beneficiaries.

To the extent that the Medicare payment exceeds the eligible organization's adjusted community rate under a risk-sharing contract, the organization must use the savings to provide its Medicare members with additional benefits (selected by the organization and approved by the Secretary) or reduced cost sharing.

For organizations that had cost contracts on the effective date or the new Section 1876 and switch to a risk-sharing contract, they will be required to enroll two new Medicare members for each current Medicare enrollee who converts to risk reimbursement.

The Secretary may enter into reasonable cost contracts with eligible organizations which he or she determines do not have the capacity to bear the risk of potential losses under a risk-sharing contract, or which so elect, or which do not meet the membership size limitation.

The Secretary is required to conduct a study on the benefits, in addition to Medicare benefits, which are provided under the new risk reimbursement; and another study on the extent of, and reason for, Medicare beneficiaries terminating membership in HMOs.

Effective Date: The provision will become effective the later of the first day of the thirteenth month after enactment, or one month after the Secretary notifies Congress that he is reasonably certain that the methodology for determining the prospective rate based on 95 percent of the AAPCC is developed and can be implemented.

I. FRAUD AND ABUSE CONTROL ACTIVITIES

During FY 83 HCFA's only involvement with Medicaid/Medicare fraud was the referral of potential fraud cases to the Office of the Inspector General for possible criminal prosecution, or to the Department of Justice for possible civil prosecution. HCFA's attention had been focused on the detection and prevention of abuse in the Medicaid/Medicare programs with concerted efforts in the areas of:

- o integrity involving preliminary case development and abuse case processing;
- o administrative sanctions activities (terminating/excluding/suspending certain physicians or practitioners from participation in the Medicare program);
- o quality assurance programs;
- o increased efforts in various validation reviews;
- o identifying overpayments and savings;
- o applying computer technology to detect patterns of fraud and abuse; and
- o legislative proposals.

In January 1983, the Medicare fraud and abuse functions formally located within HCFA was transferred to the Office of the Inspector General (OIG). Future figures regarding the above areas on fraud, abuse, investigations, overpayments and savings will be reported by the OIG in their semi-annual report to Congress. The Administrative sanction authority was also transferred to the OIG in January 1983. Data regarding this authority will also be reported semi-annually to Congress.

QUALITY ASSURANCE PROGRAMS

Contractor Performance Evaluation Program (CPEP)

As part of their claims processing and provider reimbursement functions, contractors are responsible for identifying and referring for appropriate actions, cases of suspected fraud and abuse. In FY 1983, the CPEP included measures to assess the effectiveness of contractor performance in fulfilling their responsibilities to safeguard Medicare Trust Funds from fraudulent or abusive activities.

In this program, specified criteria are used to measure contractor Part A (hospital insurance) and Part B (medical insurance) performance in the areas of: bill processing (claims processing - Part B), utilization safeguards -Part B only, provider reimbursement (program payment -Part B), beneficiary services, fiscal administration, and general administration. These criteria are applied uniformly to all contractors within each program. Standards for unit cost of bill (claim) processing, timeliness of bill (claim) processing, timeliness of cost report settlements (Part A only), and quality of claims processing (Part B only) were also established. The process of applying standards and criteria to intermediary performance began on October 1, 1979. Carrier performance initially became subject to the application of standards and criteria on October 1, 1980. Each subsequent year the standards and criteria have been revised and refined to more accurately measure contractor performance.

The CPEP is administered through HCFA's ten regional offices. Throughout the fiscal year, the regional staffs evaluate contractor performance by conducting onsite reviews and analyzing performance data. At the end of the year, Annual Contractor Evaluation Reports (ACERs) are prepared citing CPEP results and are published by the regions of each contractor in their service area.

HCFA uses the results of the application of CPEP criteria and standards to the contractors' performance to identify the contractors having deficient performance. When combined with historical perspective, this process has proven to be an effective tool for identifying those contractors exhibiting a pattern of continuing poor performance with little or no apparent improvement. Establishment of performance goals and monitoring systems, and the practice of conducting face-to-face meetings between senior HCFA staff and executives of poor performing contractors, have achieved overall improvements in contractor operations.

The program integrity performance levels for intermediaries (Part A) seek to ensure that:

1. desk reviews of provider cost reports are performed to verify that providers are receiving appropriate program reimbursement;
2. full-scale indepth audits are performed when appropriate;
3. improper or nonallowable costs are identified and necessary adjustments are made;
4. instances of potential fraud and abuse are identified and referred for investigation; and
5. sanction action (exclusion or termination from participation in the program) is taken when appropriate.

The program integrity performance levels for carriers (Part B) seek to ensure that carriers:

1. monitor the Medicare claims experience for all individual and group physician/suppliers, and acquire statistical data on them and their specialty groups;

2. identify and review those physicians by locality and specialty whose utilization patterns differ from medically recognized standards, criteria and norms;
3. correct any program abuse or overutilization of provider service by recovery of overpayments;
4. prevent further abuse in the utilization of services by educating physicians/suppliers in the acceptable norms of practice;
5. identify those individual providers or types of services where prepayment controls are necessary;
6. refer cases for sanction action (exclusion from participation in the Medicare program) if corrective action has been unsuccessful; and
7. properly handle and refer for investigation, fraud and abuse complaints received from beneficiaries, interested parties, or other sources.

Of 13 Medicare contractors identified as poor performers in FY 80, one was given an unconditional contract renewal for FY 81 due to significant improvement in performance. Four contractors were given special limited contracts to facilitate future consolidations of workload. Three contractors continued to be on probation, having been given a one-year contract. The remaining five contractors received letters of admonition citing deficient performance and required improvements. Meetings were held with two contractors to discuss long-range improvements in performance. One other contractor, first identified as a poor performer in 1977, was given a special limited contract until an adjacent contractor could assume its service area.

In 1981, 24 poor performing Medicare contractors (including field office sites) were identified by utilizing results from the Part A CPEP and three years of performance data for the Part B carriers. Nine of the 24 contractors had been previously identified in 1980. Of these nine, HCFA replaced one contractor through the nonrenewal process after a history of high cost and poor quality claims processing; two contractors were again given special limited contracts pending workload consolidations; two contractors continued to be on probation; four contractors continued FY 81 marked the first year that both intermediaries and carriers, including those in probationary status, were expected to meet the criteria and standards. Any contractor with deficient performance during FY 81 and having a past history of poor performance would be subject to, possible adverse action or other administration actions designed to achieve improved performance.

As part of their claims processing and provider reimbursement functions, contractors are responsible for identifying and referring for appropriate actions, cases of suspected fraud and abuse. In FY 1983, the CPEP included measures to assess the effectiveness of contractor performance in fulfilling their responsibilities to safeguard Medicare trust funds from fraudulent or abusive activities.

Cost Report Evaluation Program (CREP) - Part A

The Cost Report Evaluation Program (CREP) is a comprehensive review program, designed to evaluate the quality of the settlement of provider cost reports (Part A - Title XVIII) by Medicare intermediaries. CREP has been in operation since FY 79 and is now beginning its fifth year.

CREP was initially designed to evaluate hospital cost report settlement and this is still its primary focus. In recent years, the program has been expanded to include home health agency (HHA) settlements.

CREP scores are fed into Contractor Performance Evaluation Program (CPEP) as the only evaluative measure under intermediary audit and reimbursement functions. (CPEP is operated by HCFA's Bureau of Program Operations which evaluates all contractor functions.) The major objectives of the program are to:

1. ascertain that intermediaries are settling cost reports in accordance with program regulations, policies and instructions,
2. discover errors and recoup program monies where applicable,
3. identify the underlying cause of significant errors or problems and make recommendations for improvement, and
4. identify areas in the regulations, instructions, and policies which are either not clear or require clarification or revision.

The reviews are performed by the ten HCFA regional offices, with central office assisting when necessary. Central office staff is responsible for reviewing HCFA's Office of Direct Reimbursement intermediary functions.

The CREP, which is starting its fifth year of operation, was originally designed to evaluate Medicare hospital settlements. There are approximately 6,800 hospitals in the United States which received about \$36 billion as payment for inpatient services to Medicare beneficiaries. CREP is the only program that consistently evaluates this significant cash flow stream. CREP is to be expanded to include Home Health Agency (HHA) settlements, a Systems Test for Alternative Reimbursement (STAR), and will expand into Long Term Care facilities and chain operations.

The program is based on a valid statistical sample of provider cost reports that were settled by Medicare intermediaries within certain designated periods. The program consists of a series of objective procedures that are designed to evaluate significant areas of provider cost reimbursement. Regional office reviewers are required to evaluate all applicable areas based on their analysis of cost reports, desk reviews, intermediary workpapers, permanent files and other pertinent documentation. At the conclusion of the review, a report of findings and recommendations is issued to each intermediary. The report also includes a score which is based on the regional evaluation of the procedure.

During FY 83, there were 25 intermediaries reviewed. The total number of hospital providers reviewed was 182 and the total number of HHA providers reviewed was 44. Total estimated dollar findings were 6.6 million.

Medicare Part B Quality Assurance Program

The Part B Quality Assurance program was designed to provide a statistically valid and objective procedure for evaluating carrier claims processing performance. The carrier performance measurements data are obtained through systematic carrier reviews of samples of adjudicated claims drawn from each carrier's universe of Part B claims. Regional office subsample reviews verify the accuracy of the performance data from the carrier reviews. Data are provided on the number and type of processing errors and associated dollar amounts for each carrier's claims processing operation and compared on a national basis through consolidating rankings. The data generated constitute an integral part of the Contractor Performance Evaluation Program (CPEP) which, in turn, is a primary mechanism for determining carrier contract renewal, discontinuance, or required program improvements. The quality assurance program also provides carriers with a management tool to improve the quality of their claims processing operation and, in addition, gives HCFA a useful basis for modifying policies and adjusting procedures in the development of a more cost effective and efficient Medicare program.

A national quarterly report is published which ranks carriers based on the cumulative error rates assessed during the most recent 12-month period. Carriers are ranked both on occurrence error rate (processing errors per 100 line items in the universe) and on payment/deductible error rate (dollar errors per 100 dollars of submitted charges in the universe). A penalty figure is included in the payment/deductible error rate when a carrier fails to review all sample claims selected.

The following information is for FY 1983:

- o Thirty Medicare Part B carriers (44 processing sites) processed 169 million claims with submitted charges totaling \$23 billion. Normally 39 carriers (53 processing sites) operate Medicare Part B, but all did not submit data timely.
- o Carrier occurrence error rates were ranged from 2.2 to 12.2. The mean occurrence error rate was 6.1.
- o Carrier payment/deductible error rates ranged from 0.6 to 2.3. The mean payment/deductible error rate was 1.5.
- o Payment/deductible dollar errors, representing overpayments and underpayments and misapplication of the deductible, totaled \$338 million. The mean number of payment/deductible dollar errors was \$7.7 million.

During FY 83, the total payment/deductible error rate with penalty decreased 0.2 percent from FY 82. The mean carrier error rate decreased from 1.7 to 1.5 percent. A savings to the Medicare Part B program of \$43 million occurred in this period due to a decrease in the national overpayment error rate. This is an atypical savings figure because of the unexpectedly large reduction in the national overpayment error rates. Future savings are not expected to approach this level. The FY 1983 national error rate, based on 44 of 53 carrier locations reporting, was 0.79. This indicates that \$0.79 was estimated to be overpaid per \$100 of submitted charges. For FY 82, this error was 0.96.

Chain Operations

In FY 83, HCFA has continued its efforts to improve its ability to cope with the complex activities of the chain organizations and to properly relate these activities to Medicare reimbursement process.

Target Rate Implementation Monitoring (TRIM) Program

The TRIM program is a review program designed to concurrently monitor the quality of the base year audits and computations of the target amount per discharge under the Prospective Payment System. The major objectives of the program are to:

- o Determine if the intermediaries are performing the base year audits and establishing the target amount per discharge under PPS in accordance with HCFA regulations, policies and instructions.
- o Effect an immediate corrective action by the intermediary upon detection of significant errors or problems.
- o Identify area in HCFA's policies and instructions which may require modification.

The evaluation of the intermediaries' performance will be accomplished through a review of the crucial phases of the target amount per discharge (rate) determination process, namely: (1) fiscal/resource planning, (2) preaudit, (3) audit, and (4) rate calculation and notification.

To ensure that the program objectives are met, the regional office has the primary responsibility for reviewing, evaluating, and determining the adequacy of intermediaries' performance and providing suggestions for program and policy improvement.

Program Validation

Effective in FY 83, the function of Program Validation was assumed by the Office of Inspector General (OIG). The statistical data on savings, fraud, abuse, waste, etc., are reported by OIG in their Annual Reports to Congress.

Black Lung Overpayments

HCFA identified substantial overpayments, involving millions of dollars per year, with respect to services that should have been paid for by the Department of Labor (DOL) under the Black Lung program. Instances of payments by both programs for the same services were also identified. HCFA was instrumental in establishing arrangements with DOL to permit recovery of overpayments from DOL rather than from the beneficiary or the provider. In June 1983 procedures were implemented which identify dually entitled beneficiaries and prevent Medicare payments where DOL has responsibility for payment.

Computer Technology

Software programs have been developed to detect instances of fraud or abuse in the Medicare and Medicaid programs. These programs have detected inconsistent billing practices in the Part A and Part B files; Part A, Part B, and Medicaid files; Part A and Black Lung files; and Part A and Worker's Compensation files.

Legislative Proposals

Several significant legislative proposals were developed in FY 83, including:

- o Denial of Payments to a Provider for Services Ordered by a Sanctioned Physician

This proposal would authorize the Secretary to deny reimbursement under Medicare and to deny Federal Financial Participation under Medicaid for all items and services ordered by a physician during the period that such physician was suspended or excluded from Medicare program participation under existing authorities. The proposal would also allow denial of Medicare reimbursement and Federal Financial Participation under Medicaid for inpatient services whenever the patient was admitted to the provider of such services by a suspended or excluded physician. Current authorities prohibit Medicare and Medicaid reimbursement directly to a suspended or excluded physician. However, the sanctioned physician may continue to abuse the Medicare and Medicaid programs by ordering unnecessary or excessive items or services and unnecessary hospital admissions for beneficiaries and recipients. This proposal would address this problem.

- o Secretary's Authority to Terminate a Provider's Agreement

This proposal would enable the Secretary to terminate those health service providers owned, controlled, or operated by an individual who has been convicted of a criminal offense related to his/her involvement in the Medicare or Medicaid program. This proposal is needed to correct a technical deficiency in current similar authorities.

- o Denial of Program Participation to Entities Where Owners or Certain Other Individuals Have Been Convicted of a Program Related Offense

This proposal would correct a gap in existing legislation. The Secretary would be allowed to deny program participation to suppliers and other entities where a person, with significant ownership or control interest in the supplier or other entity, or who is an officer, director, agent, or managing employee of the entity, has been convicted of a program-related criminal offense.

- o Require that States Obtain Social Security Numbers as a Condition of Receiving Medical Assistance

This proposal would require that Social Security numbers be obtained from Medicaid applicants and recipients in order to deter fraud, reduce errors in eligibility determination and facilitate efficient administration.

J. BENEFICIARY SERVICES

Established in December 1979, the primary objectives of the Office of Beneficiary Services (OBS) are:

1. Inform beneficiaries about HCFA programs, and their rights and responsibilities.
2. Open channels of communication between beneficiary representative groups and HCFA.
3. Improve services provided to beneficiaries by contractors, State agencies and Social Security offices.

HCFA's redesigned Explanation of Medicare Part B Benefits (EOMB) became effective in 1983. The new EOMB reflects the inputs from a wide variety of organizations representing beneficiary groups. The revised notice has been simplified and contains information that can be easily understood by Medicare beneficiaries.

HCFA's Physician/Supplier Assignment Rate List (PARL) became effective in 1983. This annual listing of physician/supplier assignment rates reflects the informational requirements of numerous beneficiary organizations. The list will be revised annually for both the content and format, in order to ensure that it can be easily used by the maximum number of beneficiaries.

Medigap

HCFA has developed an education program to better inform Medicare beneficiaries about (1) Medicare coverage, (2) the major gaps in Medicare coverage, (3) the various types of private health insurance assigned to supplement Medicare and (4) comparative shopping hints to use when purchasing private supplemental health insurance. To implement this initiative, OBS designed, developed, and produced the 68-page training text, Medicare and Private Health Insurance, based on a pamphlet developed jointly with the National Association of Insurance Commissioners (NAIC). This text, plus accompanying visual aids and checklist for comparing policies, served as the basic material for a nationwide program to train counselors and volunteers who, in turn, assist Medicare beneficiaries on private health insurance decisions. To date, HCFA regional office Medigap coordinators (who received their initial Medigap training at central office) have conducted more than 800 training sessions in all 50 States, the District of Columbia and Puerto Rico. Approximately 40,000 attendees have received Medigap training through this program. A continuation of another facet of the Medigap initiative has been the distribution of over 9 million copies of A Guide to Health Insurance for People with Medicare, the information pamphlet which was first produced in 1979 in conjunction with NAIC.

Updating, Revising, and Improving Beneficiary Informational Material

OBS revises and updates Your Medicare Handbook semi-annually and same 20 other Medicare pamphlets at least annually. Six million copies of Your Medicare Handbook were printed and distributed to Social Security offices, Medicare Contractors and new Medicare enrollees during FY 83.

Liaison With Beneficiary Organization

OBS maintains an ongoing program of liaison with beneficiary organizations. In addition to soliciting beneficiary organization input and participation in the development of program policy procedures through briefings and personal liaison, Medicare periodically mails materials to national beneficiary groups to keep their membership informed about current Medicare benefits and coverage. OBS representatives also attend national organization conferences and meetings, and participate in workshops, panel discussions and forums on Medicare-related issues.

Beneficiary Casework

OBS continued to function as a central office ombudsman for special beneficiary inquiries and problem cases. Most inquiries are telephone referrals from the Office of the Administrator, HCFA; Office of the Secretary, HHS; the White House; and Congress. Many inquiries come directly from beneficiaries seeking help with errors in their records resulting in loss of eligibility or incorrect premium billings necessitating a review and correction of their Medicare records. There is also a high incidence of complaints about what are seen as deficiencies in program coverage; e.g., the lack of prescription drug or nursing home coverage under Medicare. In such cases, efforts are made to guide the caller to other resources for financing the necessary medical services. Other inquiries relate to difficulties with Medicare contractors and problems involving submission of, and reimbursement for, Medicare claims. In all these instances, the ombudsman function provides a valuable service for Medicare and Medicaid beneficiaries, many of whom have difficulty dealing with the complexities of these programs.

Beneficiary Services Awards

The Beneficiary Services Awards were established to provide special recognition to individuals or groups for either outstanding performance in service to beneficiaries or for a major contribution in the area of beneficiary services. The awards serve to provide an incentive to develop innovative ideas, resources, and programs in assisting beneficiaries.

HCFA recognized outstanding beneficiary service awardees selected in FY 83 as part of as part of HCFA's Annual Awards Ceremony.

Telephone Directory Listings Under Medicare

In September 1982, all Medicare Part B contractors were instructed to have their local and toll-free telephone numbers displayed with "Medicare" in the White Pages of the telephone directories which cover their service areas.

SSA District Office Final Adjudication of ESRD Initial Claims

In November 1981, the SSA district offices were given the capability to take final adjudicative action on certain initial end-stage renal disease (ESRD) awards. HCFA proposed this change in procedure and coordinated its implementation with SSA. District office final authorization has resulted in a decrease in processing time for initial ESRD awards. Many ESRD patients now have Medicare records established more quickly and medical bills for dialysis or transplant can be processed with less delay.

Centralization of the Direct Billing and Collection Operation

Until September 1982, the Social Security Administration printed and mailed bills from its Baltimore headquarters to approximately 825,000 Medicare beneficiaries who are billed directly for their Medicare premiums. These punch card bills and premium payments were then returned to eight different SSA Program Serviced Centers for processing.

As of September 1982 this punch card operation was converted to a centralized lockbox operation; that is, all premiums are paid to and processed by a private bank. This approach has several advantages. Beneficiaries are provided a portion of the new bill as a receipt, the bill is easily readable and is processed using automated equipment. In addition, beneficiaries now receive the bills at least five days earlier and all funds collected by the lockbox bank are deposited to the Treasury Department within 72 hours. The conversion of the operation to a lockbox resulted in yearly savings of about \$1, 550,000.

K. MEDIGAP VOLUNTARY CERTIFICATION PROGRAM REPORT (Section 1882(i)(2) of Title XVIII)

Background

Congressional studies conducted prior to 1980 found many abuses existing in the sale and marketing of Medicare supplement or "Medigap" health insurance. There were no federal standards for medicare supplement coverage and few States had adopted programs to specifically regulate these types of policies. In June of 1980, Congress enacted P.L. 96-265 which added Section 1882 to Title XVIII of the Social Security Act. This law, usually referred to as the Medigap Law, initially was staunchly opposed by insurance regulators and the insurance industry. The regulation of the business of insurance has traditionally been the responsibility of the States under the McCarran-Ferguson Act of 1945 and the Medigap law was perceived by some as an encroachment upon States' rights. This perception resulted from a fear that the Federal government would necessarily have to become greatly involved in individual insurance department operations in order to enforce the law. This has not proved to be the case, however, and the relationship between the Federal government and the States has been a cooperative one. State and Federal agencies are working together toward our common goal of providing the best protection available for our elderly citizens.

The Medigap law established federal minimum standards based primarily on the provisions contained in the 1979 National Association of Insurance Commissioners (NAIC) Model Regulation to Implement the Individual Accident and Sickness Insurance Minimum Standards Act. The law, however, expands upon the Model's requirements by extending its jurisdiction to certain group policies and by adding loss ratio requirements for both group and individual policies. In addition, it provides for the establishment of the Supplemental Health Insurance Panel, a Federal Voluntary Certification Program for Medicare supplement policies, and includes criminal penalty provisions for certain abusive sales practices.

Voluntary Certification Program

Under this program, insurers selling Medigap policies in these States may voluntarily submit such policies to be reviewed by the Secretary of the Department of Health and Human Services (DHHS). Those policies found to meet or exceed the Federal minimum standards would be certified and the insurer would be authorized to display a Federal emblem on the policy. The emblem is authorized for use only in States subject to the Federal program, regardless of whether the same policy is marketed in other States not under the program.

The Medigap Law also established Federal criminal penalties for certain fraudulent or abusive marketing practices. Criminal sanctions are provided for furnishing false or misleading information for the purpose of obtaining certification; for misrepresentation as an agent of the Federal government for the purpose of selling insurance to supplement Medicare; for knowingly selling insurance which substantially duplicates benefits of another policy held by the purchaser; and for knowingly advertising, soliciting, or offering for sale mail order policies in a State without the approval of the State Insurance Commissioner. Anyone convicted of violations of Section 1882 is subject to a fine of up to \$25,000 and/or imprisonment for up to 5 years.

Reporting Requirements

Section 1882(f)(2) of the Social Security Act requires the Secretary to submit to Congress no later than July 1, 1982, and periodically as may be appropriate thereafter (but not less than once every 2 years), a report evaluating the effectiveness of the certification procedure and the criminal penalties established under this section.

1. Voluntary Certification Program

The Supplemental Health Insurance Panel determined that the Voluntary Certification Program should be implemented in the following 4 States and 3 Territories: Massachusetts, New York, Rhode Island, Wyoming, Guam, the Virgin Islands and American Samoa.

Only two insurers have submitted policies for review under the Voluntary Certification Program and no policies have been certified to date. While the deficiencies noted in the policies submitted were seemingly minor, the insurance companies involved have not re-submitted the policies or indicated that they have made the necessary changes. Other insurers have expressed interest in the program, however, and it is felt that if one insurer were to market a certified policy, others would soon follow suit.

The fact that the Voluntary Certification Program applies only to a very few States and jurisdictions, in itself, limits the direct impact that such a program may have. In this same respect, however, the Voluntary Certification Program was responsible for the overwhelming success of the Medigap Law, since it served as the incentive for such a large number of States to adopt their own programs regulating Medigap policies. Indeed, the number of States adopting the 1979 NAIC Model is the largest number ever to adopt any NAIC model.

In addition to the small number of States involved, there are other possible reasons for such a limited reaction to the program. Foremost is the perception on the part of the state insurance regulators and the insurance industry that such a program is an infringement upon the individual States' right to regulate the business of insurance. As noted earlier, the Federal-State relationship resulting from the Medigap Law has proved an amiable one, but there is still much apprehension in the insurance community about a "federal" emblem being placed on a private insurance policy. It is felt that the emblem may encourage the practice of "twisting" where insurance agents replace existing coverage with new coverage that offers no greater benefits or even lower overall benefit levels. Some insurers also feel that the emblem may serve to confuse some elderly Medicare beneficiaries since it may appear only on those policies sold in States subject to the Voluntary Certification Program.

Most insurers design their Medigap policies to be marketed in a number of States. So a situation would exist where a policy would be able to display the emblem in a State under the federal program, but the exact same policy could not bear the emblem in a State that was not under the program. The additional costs involved in preparing policies for distribution in just a few States also is a deterrent to seeking certification.

Conclusion

Since the Secretary has not yet certified any policies under the Voluntary Certification Program, there is no data available to show the direct impact of the certification procedure on market share, value, and cost to individuals entitled to benefits under Title XVIII. As stated earlier however, the indirect impact of the program has been its very positive effect of prompting the States to implement their own approved regulatory programs for Medicare supplement policies. Without the Voluntary Certification Program serving as an incentive, it is doubtful that there would have been as many States making changes to their existing programs. Also, the Supplemental Health Insurance Panel is now responsible for monitoring the continued compliance of the approved States and the Voluntary Certification Program should act as a deterrent to those States considering changes to their regulatory programs that would adversely affect their continued compliance with the Medigap Law. At the present time it seems to be in the best interest of all concerned to continue the Voluntary Certification Program as set out in Section 1882.

2. Penalty Provisions

The Health Care Financing Administration (HCFA), given the responsibility for implementing the penalty provisions of the Medigap Law, continues to investigate possible violations of Section 1882(d). HCFA has developed a system of coordination for reporting these violations which includes the ten HCFA regional offices, the Social Security Administration (SSA), the Office of the Inspector General (OIG) for Department of Health and Human Services, and the Department of Justice (DOJ).

The initial screening of complaints is generally done through HCFA's regional offices. These offices are also responsible for furnishing information to State insurance departments about specific complaints. The OIG investigates complaints that have been referred to them by HCFA and coordinates this activity with State insurance departments. OIG also serves as the liaison between State insurance departments and the U.S. Attorneys, who have been contacted by the Fraud Division of DOJ regarding the Medigap Law and encouraged to prosecute violations of this section.

During FY 83, HCFA was informed of 16 possible violations of the penalty provisions. Fifteen of these, or 94 percent, involved Section 1882(d)(2) which prohibits a person from falsely representing an association with the Medicare program or any Federal agency for the purpose of selling or attempting to sell health insurance. One case involved an alleged violation of Section 1882(d)(3) which prohibits a person from knowingly selling duplicative health insurance to an individual entitled to Medicare, where such a policy will not pay duplicate benefits. Of the complaints received: Seven are being or have been investigated by specific State insurance departments, were closed by HCFA due to lack of evidence, two are being investigated by or have been investigated by the OIG. One case investigated by the OIG and the FBI resulted in the indictment of three insurance agents in Pennsylvania in September 1982. Additionally, HCFA was able to close out 21 cases which were pending during prior fiscal years. Of these cases, fifteen were closed by State Insurance Departments for lack of evidence, and six resulted in State Administrative Sanctions.

HCFA also receives many complaints which, while not in violation of the Medigap law, are possible violations of other federal statutes. These most often involve misleading advertising and mail order solicitations for Medicare supplement insurance. HCFA's efforts in this area are being coordinated with other federal agencies such as the Federal Trade Commission and the Postal Inspection Service.

Conclusion

Witness reliability has continued to be a problem in getting cases prosecuted under Section 1882. The elderly often become confused under questioning and prosecutors are reluctant to charge agents under federal law, since criminal penalties are called for. They feel that administrative penalties are more appropriate in many cases.

There is still a great deal of interest at the State level in utilizing the federal penalties to prevent abuse and fraud in the sale and marketing of Medigap policies. Most States still do not have specific laws for violations involving Medicare supplemental health insurance. As we indicated, however, getting these types of cases prosecuted under federal law has proved difficult. At the present time it is felt that it is in the best interest of our elderly citizens to continue the penalty provisions of Section 1882. Even though there have been no convictions to date under this law, the option of prosecution under federal law should remain available.

L. IMPLEMENTATION OF THE MEDICARE PROSPECTIVE PAYMENT SYSTEM

Effective with hospital cost-reporting periods beginning on or after October 1, 1983, Medicare payment for inpatient operating costs became based on a fixed amount, determined in advance, for each case, according to one of 468 diagnosis related groups (DRGs) into which a case is classified. The prospective payment is considered payment in full; hospitals are prohibited from charging beneficiaries more than the statutory deductible and coinsurance.

This system replaced the retrospective cost reimbursement system and the cost-per-case limits and rate of increase ceiling created by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), P.L. 97-248, for most hospitals. The new prospective payment system is structured to be "budget neutral" through FY 1985; that is, payments for Medicare inpatient hospital costs under the prospective payment system can be no more or less than projected under the TEFRA provisions.

A major operational planning and systems development effort was required during FY 1983 to ensure that all effected providers and fiscal intermediaries were ready for the conversion of the first group of providers to PPS effective October 1, 1983. Significant operational tasks developed and implemented during FY 1983 included:

Provider and Contractor Training - Training was conducted in two phases. The first phase consisted of general introductory sessions. Subsequent to several national sessions for regional offices and contractors, general management orientations were conducted for all providers. The second phase entailed detailed claims processing, medical review and audit and reimbursement training for provider personnel. Training was scheduled on a staggered basis, relative to the provider conversion date to prospective payment.

Claims Processing and System Changes - This activity required insertion of computer software into the intermediary's processing system to group and pay claims based on a diagnosis related group. In addition, additional edits and systems interfaces were developed and incorporated into the claims processing system. Standardized "Grouper," "Pricer" and "Medicare Code Editor" software packages were developed and made available to intermediaries to assure uniform system modifications. Comprehensive claims processing instructions were developed to facilitate the contractor's conversion and technical assistance provided.

Audit and Reimbursement - The legislation stipulated that a portion of the prospective payment rate must relate to each hospital's own experience during a base cost reporting period. In order to establish this hospital specific rate, an audit was conducted of each PPS hospital's base period cost report. In conjunction with intermediary advisory groups, HCFA developed an audit protocol, provided seminars for intermediaries on specific audit procedures and issued comprehensive instructions to facilitate calculation of the hospital specific rate. In addition, instructions were issued to explain modifications to the desk review, audit and settlement process, as well as instructions focusing on specific reimbursement issues relating to the base period.

This comprehensive operational implementation planning effort has enabled virtually all hospitals to convert to prospective payment without experiencing significant cash flow or operational disruption.

M. OPERATIONAL REVIEW ACTIVITY

In FY 1983, all program integrity functions were transferred to the Office of Inspector General. HCFA retained primary responsibility for operational reviews which assess the need for policy and operational reforms in vulnerable program areas. In order to provide HCFA senior management with the financial and operational implications of their policy and management decisions, HCFA staff:

- o perform pilot studies of selected program and policy issues through the review of in-house information, supplemented by additional on-site documentations to determine potential for expansion into national reviews
- o prepare detailed review guides, manual instructions, quarterly reports, special studies, summary issue papers, and management briefings

During FY 1983 operational reviews were initiated in the following areas:

- o Parenteral/Enteral Services--This review should focus upon the coverage and reimbursement of parenteral and enteral services and supplies as well as contractor claims jurisdiction.
- o Medicare Secondary Payer--This review should examine provider methods and procedures for correctly identifying situations in which Medicare is the secondary payer.
- o Pacemaker Replacements--This review should focus upon current reimbursement guidelines for replacement pacemakers.
- o Survey and Certification--This review should identify providers which have recurring problems meeting certification requirements. The review will attempt to determine whether these providers have common characteristics which would enable State survey teams to identify them for review.
- o Medical Review/Utilization Review--This review would identify the most productive screens with a view towards recommending their use nationwide.

CHAPTER III. REPORT ON RESEARCH, DEMONSTRATIONS AND STATISTICS

Data for this period show that total spending for all health care expenditures in the United States rose from \$75.0 billion in calendar year 1970 to \$355.1 billion in calendar year 1983, an average annual rate of increase of 12.7 percent forthcoming (Health Care Financing Review, Winter 1984).

- o Medicare's share of all national health expenditures rose from 10.0 percent in 1970 (\$7.5 billion) to 16.5 percent in 1983 (\$58.8 billion).
- o Medicaid's share of all national health expenditures rose from 7.3 percent in 1970 (\$5.5 billion) to 10.10 percent in 1983 (\$35.7 billion).

During FY 83, HCFA's Office of Research and Demonstrations (ORD) directed over 350 intramural and extramural projects that studied, demonstrated, and evaluated reimbursement, coverage, eligibility and issue alternatives to the present structure of the Medicare program. ORD measured and evaluated the impact of HCFA's programs on (1) beneficiary use of program benefits and access to services, and (2) provider charges and program reimbursements for the use of these benefits. HCFA approved over 60 new projects as part of its ongoing research, of the demonstrations and evaluation program in FY 83. These activities are described below in the major research and demonstration program areas. Following that discussion is a section devoted to data base and statistical activities and a description of HCFA's publications program.

Research, Demonstrations, and Evaluations

Research and experimentation in support of the Medicare program is authorized in the Social Security Act and the Social Security Amendments of 1967 and 1972, as well as in the National Health Planning and Resources Development Act of 1974. HCFA develops and tests innovative ways to promote efficiency and quality in the Medicare and other HCFA programs. It assesses the impact of HCFA programs on health care costs, program expenditures, beneficiary access to services, health care providers, and the health care industry. Reports are written to describe and analyze the use and costs of program benefits. Studies are undertaken to explore in greater detail the structure and dynamics of the various sectors of the health care industry.

During FY 83, HCFA spent almost \$30 million for grants and contracts to conduct research, demonstration, and evaluation projects. The program areas that had been used in the past were revised and combined as follows:

New Program Areas

Hospital Payment

Physician Payment

Long-Term Care

Old Program Areas

Hospital Costs

Physician Reimbursement

Long-Term Care

Alternative Payment Systems	Health Systems Organization Industrial Organization Hospital Costs
Program Analysis and Evaluation	Program Evaluation Beneficiary Impact Integrated Data
Coverage	Health Systems Organization
Prevention	Quality and Effectiveness Health Systems Organization

Although projects discussed in this report relate primarily to Medicare, information regarding Medicaid is also provided where it enhances the information being presented. Additional information on HCFA research and demonstration projects can be obtained from the HCFA publications office identified at the end of the chapter. (See Page 96)

1. HOSPITAL COSTS

In the fiscal year ending September 1983, community hospital expenses were 12.2 percent higher than in the previous year, and Medicare reimbursement under Part A rose 10.9 percent. These growth rates occurred at the same time that the gross national product, a measure of our nation's output and our purchasing power, grew only 7.7 percent.

Prospective Payment

In FY 1983, HCFA's Research, Demonstrations, and Evaluation Program was largely dedicated to assembling information that could be used to attack spiralling hospital and Medicare Part A costs. In P.L. 97-35 (OBRA), Congress directed the Secretary to develop a model prospective payment system which States might use as an alternative to retrospective cost reimbursement.

Yale University completed its development of "Diagnosis-Related Groups (DRGs) Based Upon ICD-9-CM." This project provided a case-mix measurement tool which would be used in the implementation of the Medicare Hospital Reimbursement reform required by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) which changed the Medicare unit of payment for routine inpatient care costs to a total operating costs per discharge, as opposed to per day. This revised system was also implemented by the State of New Jersey for its hospital cost control mechanism. Substantial amounts of intramural analyses were devoted to methods for establishing diagnosis related group cost-weights for measuring Medicare case-mix.

HCFA's Office of Research and Demonstrations developed the Secretary's Report to Congress on Prospective Payment Systems for Hospital Care which was delivered to Congress in December 1982. Besides providing a useful technical guide for States considering the implementation of their own prospective payment programs, these analyses also contributed to formulation of the options for a Medicare prospective payment program, which the TEFRA legislation requested be reported to Congress by December 31, 1982. HCFA's Office of Research and Demonstrations also prepared the Secretary's Report to Congress on Hospital Prospective Payment for Medicare, which was delivered to Congress in December 1982. HCFA's Office of Research and Demonstrations also prepared the Secretary's Report to Congress on Hospital Prospective Payment for Medicare, which was delivered to Congress in December 1982.

A special single-theme issue of the Health Care Financing Review was prepared for December 1982. The theme was prospective payment, and the five research articles included presented results from individual States' reimbursement programs.

HCFA continued its participation in six hospital prospective payment demonstrations through Medicare and Medicaid waivers of standard Medicare Medicaid reimbursement principles. Medicare and Medicaid waivers were in effect statewide in Maryland, Massachusetts, New Jersey, and New York.

Medicare and Medicaid waivers were also in effect in two voluntary hospital payment programs in the Rochester and Finger Lakes areas of New York State. These projects continued to provide insights into various alternative reimbursement methodology options and were of significant value in the deliberation on Medicare's new prospective payment system that was enacted during FY 1983.

In 1983 HCFA extended the period for both the Maryland and New Jersey statewide hospital payment projects under the research and demonstration authority of Section 402 of the Social Security Amendments of 1967. These projects were extended to allow sufficient time for regulations to be promulgated for Medicare's new program waiver authority for statewide hospital payment systems contained in Section 1886(c) of the Social Security Act. Both Maryland and New Jersey can file for continuation of their State systems under the Medicare program waiver authority as an operational program with no requirements to demonstrate a research objective.

Outpatient

Research projects continued data with Brandeis University and the American Hospital Association to gather data and analyze hospital outpatient department cost and performance. A contract was awarded to Mandex, Inc. to identify those services which were commonly performed both in physician office and hospital outpatient departments. The eventual goal is an ambulatory care payment system that complements the hospital inpatient care payment system.

Data Development and Analyses

Projects were also continued with the American Hospital Association to obtain hospital service and financial information, with Applied Management Sciences for statistical and analytic support of intramural hospital reimbursement studies, and with the Commission on Professional and Hospital Activities to obtain further analyses of hospital case-mix characteristics. A project with Blue Cross of Western Pennsylvania for development of Patient Management categories for hospital case-mix and cost analyses was also continued, as was a project with the Johns Hopkins University for studies of severity of hospital illnesses.

Foreign Systems

A project with the Brookings Institute for a study on the "Allocation of Resources under the Budget Constraints Imposed by the British National Health System" was extended to enable the investigators to develop their report into a full-length book.

A Columbia University project-"Paying the Hospital: Foreign Lessons for the United States"..was completed. The investigation reports covered France, Holland, Switzerland, Canada, Great Britain, and West Germany and found: (1) standardization in payment procedures and budgeting procedures lead to uniform reporting to payers and public authorities; (2) costs are the basis for paying nonprofit and public hospitals except in countries using top-downward global budgeting; and (3) payment rules, units of payment and definitions of allowable costs are generally identical for all payers.

2. PHYSICIAN PAYMENT

In response to Section 603 of P.L. 98-21, the (Social Security Amendments of 1983), research began addressing the advisability and feasibility of pursuing the implementation of prospective payment to physicians (MD-DRG's).

Physician program research was also conducted in areas other than MD-DRG's. Funding and sponsorship of ongoing grants and contracts continues. In addition, several intramural and extramural projects involving MD-DRG's were initiated during 1983.

Intramural work to examine the level and stability of outlays for physician services by DRGs in Medicare claims data samples emphasized regional, specialty and type of service patterns for high frequency DRG's. As larger data sets become available, analyses will expand to the remaining DRG's. Data file construction and specification of data display tables began in June 1983. In September 1983 a grant entitled, "Creating DRG-Based Physician Reimbursement Schemes: A Conceptual and Empirical Analyses," was awarded to the Center for Health Economics Research. This research is directed at devising DRG based prospective reimbursement for physician services and focuses on three modalities--conceptual analyses of possible alternatives in constructing DRG-based physician payments and their advantages and disadvantages; empirical analyses of Medicare Part A and B claims in New Jersey and North Carolina, as well as Medicaid in New Jersey; and case studies of hospital experience and physician responses to DRGs.

The National Opinion Research Center and its subcontractor Health Economics Research, Inc., was awarded a contract in June of 1983 to redesign and field a physicians' practice costs and income study. This project assesses the design of the survey instruments, as well as design the sample, and the data collection methodology of the 1976, 1977, and 1978 HCFA surveys of physicians practice costs and incomes. Data from this study will be used for refinements of the Medicare Economic Index.

3. LONG TERM CARE RESEARCH AND DEMONSTRATION ACTIVITIES--OVERVIEW

Total spending for nursing home care in the United States rose from \$4.7 billion in calendar year 1970 to \$20.4 billion in 1980 and \$29.4 billion in 1983 forthcoming (Health Care Financing Review, Winter 1984). This represents an average annual rate of increase of 15.0 percent. The figures below represent calendar year 1970 through 1983.

- o Together, Medicare and Medicaid accounted for 46 percent of all spending for nursing home care in 1983.
- o Medicare spent approximately \$0.3 billion in 1970, accounting for 6.0 percent of total nursing home expenditures. This increased to approximately \$0.5 billion in 1983, accounting for approximately 2.0 percent of total nursing home spending.

- o Medicare spent approximately \$82 million on home health services in calendar year 1970. This rose to \$1.7 billion in calendar year 1983, an average annual rate of increase of 26 percent.
- o Medicaid spent approximately \$17 million on home health care in 1970. This rose to \$597 million in 1983, an increase of 20 percent over 1982.

In general, HCFA's long-term care research activities involve the use and analysis of existing data, either collected by survey or abstracted from other data sources. Long-term care research has focused primarily on describing and explaining the demand for long-term care and the basic economic underpinnings of the long-term care industry. In addition, considerable effort has been given to the development of a methodology to measure the quality of long-term care provided in different settings. The purpose of this research is to develop an understanding of long-term health care delivery, reimbursement, and financing systems in order to provide some direction for private and public policymaking and to identify promising areas for demonstration activities.

ORD's long-term care demonstration experiments require the development of a rigorous research design and, within the design, a specific intervention is introduced into a live situation with subsequent observation of the outcomes. The evaluation findings, regarding the outcomes observed in our demonstrations, form the basis for future policy recommendations regarding the Medicare program.

Overview of Long-Term Care Research

The long-term care research program provides vital information relating to current and anticipated policy issues related to the goals of the Department of Health and Human Services. Most critical are those areas which provide information about how to contain costs while increasing the efficiency and rationality of the long-term care system. The research program includes congressionally mandated studies and research on fundamental issues that underlie a multiplicity of current and prospective policy questions.

HCFA's long-term care research program consists of both intramural and extramural dimensions, which are intended to be complementary. On the intramural research side, for example, we reviewed several major issues of direct and basic importance to the long-term care system in the United States. The results of this study have recently been compiled and produced in a book entitled Long-Term Care: Some Perspectives from Research and Demonstrations.

Our extramural research program is similarly oriented to provide policymakers the necessary data for enhancing policy formulation and program development. Three project areas are discussed below:

- o Determinants of Demand for Long Term Care;
- o Policy Effects on Long-Term Care Utilization and Costs;
- o Nursing Home Costs, Quality, and Reimbursement.

Determinants of Demand for Long-Term Care

Research activities were supported to explore determinants of the demand for long-term care services. Studies in this group included research on: (1) the demographic and epidemiological factors affecting long-term care, and (2) interrelationships among the elderly, their families and other informal supports and demand for long-term care services.

In the first area, Duke University studied the health status of the United States population using a model of the national history of important chronic diseases. With more accurate estimates of the prevalence and incidence of chronic diseases, better estimates of health care costs, particularly those for long-term care services, can be derived.

In the second area, projects to investigate the interrelationships among the elderly, their families and demand for long-term care services were initiated. A study by Hunter College examined the family care-giving systems of the frail elderly. It identifies factors that strengthen or weaken the family system in providing care to the elderly and recommends methods of enhancing the family care-giving system which would sustain the elderly in the community and avoid more costly alternatives.

A study was conducted by the Community Service Society in New York City in examining the effects of providing substantial ongoing home service programs to functionally disabled low income adults.

Policy Effects on Long-Term Care Utilization and Costs

Research activities were supported to clarify the relationships between policies and the utilization and costs of long-term care. Included among these were studies directed toward developing a better understanding of the components of costs for long-term care for the purpose of enhancing future policy deliberations.

One study in this group examined the behavior of physicians in long-term care. Conducted by the Center for Health Economics Research, it analyzed the factors that influence physician willingness to make nursing home visits. In particular the study examined the respective roles of Medicare reimbursement rates and Medicare disallowances on physician long-term practices.

In another group of studies, the University of Colorado and Yale University examined the relationship of case mix, quality, and costs of nursing home care. Findings from these studies indicate that groups of diagnoses and long-term care problems clustered together by facility, suggest that there are very likely specific facility groupings that emphasize care for similar types of patients. The Colorado study found that residents of hospital-based facilities were generally older and more functionally dependent than residents of free-standing facilities. The Yale study developed a patient classification typology according to resource utilization groups. In addition to the broad utility of the results of the Colorado and Yale studies in enhancing our understanding of the generic relationships between case mix, cost, and quality in nursing homes, the findings are directly applicable to specific policy related analyses.

On the basis of the findings from the nursing home survey and the data collection instruments derived for it, the University of Colorado is conducting a second study. In this 4-year project, it will evaluate nursing home and home health care providers in both free-standing and hospital-based settings. Both cost and quality of care will be assessed under four organizational arrangements.

Nursing Home Costs, Quality, and Reimbursement

Research in this area has focused on the following issues: (1) the determinants of nursing homes' costs, (2) the effect of State regulations on the supply of nursing home beds, and (3) the effect of reimbursement methods on homes' willingness to admit "costly" patients.

This research has shown that in order to make valid cost comparisons among nursing homes, it is necessary to be able to compare the types of patients they treat (case mix) and the quality of care they provide. New research in nursing home cost and quality was started in 1983 after the Robert Wood Johnson Foundation (RWJF) funded 11 university-based schools of nursing to clinically affiliate with one or two nursing homes. The purpose was to improve the health care provided to long-term care patients. HCFA, along with the RWJF funded a study of this experiment to evaluate the effects of these affiliations on patient outcomes and costs of patient care. It is expected that such affiliations will reduce hospitalization and emergency room use and increase discharges into independent living environments while decreasing nursing home stays. The results will be available in 1986.

Cost Limits for Skilled Nursing Facilities

Currently Medicare has set higher cost limits for hospital-based facilities than for free-standing skilled nursing facilities. Are the large cost differences that we observe between these two types of facilities justified by differences in the costliness of their case mixes? Or do hospital-based facilities just employ a more expensive mix of personnel to treat similar patients? The University of Colorado and Yale University (described earlier) are investigating alternative approaches to case-mix measurement that will hopefully be useful in explaining differences in nursing homes' costs.

Another University of Colorado project applied the measures developed in their earlier work specifically to the question of hospital-based versus free-standing facilities costs. (This project compares the cost effectiveness of hospital-based and free-standing facilities in providing nursing home and home health care.)

Dual Participation by Skilled Nursing Facilities

Skilled nursing facility services are provided under both the Medicare and Medicaid programs. In 1980 Congress asked the Secretary to investigate why only two-thirds of the skilled nursing facilities that participate in Medicaid also participate in Medicare. In particular, we were asked to study the impact of laws and regulations in discouraging facilities' participation in both programs and to assess the desirability of requiring dual participation.

The research found that many States provide broader, longer term Medicaid benefits than does Medicare. Medicare covers only a small part of the nursing home population for very short term convalescent care. Administrative differences between the programs, especially in reimbursement methods, also discourage facilities' participation in Medicare. The report, delivered to Congress in July 1982, attempts to both acknowledge the critical differences between the programs and to suggest ways to make them more compatible where that is feasible. The research for much of this report was conducted by the Urban Institute.

Long-Term Care (LTC) Surveys of Functionally Limited Elderly Persons

Two surveys provide a nationally representative LTC data base that is necessary for future planning and policymaking in a nation becoming increasingly more elderly. These surveys supplement the Department's Channeling Demonstration Program in order that projections of costs and the feasibility of proposed national programs can be made at the end of the demonstration period. The first survey, limited to persons living in private households in the community, was conducted in 1982 from a list of Medicare enrollees screened for functional limitations. The survey in 1984 capitalizes on the data collected in 1982 by revisiting those persons included in the 1982 survey no matter where they reside; in the community or in an institution. Data from the 1982 survey are currently being analyzed. Data from the 1984 survey provides a cross-sectional description of the prevalence and nature of functional impairments among the aged and will enable the development of estimates on the transition probabilities of movements from the community to institutions. Data from the 1984 survey will be available in late 1986.

Overview of Long-Term Care Demonstrations

HCFA also conducts demonstrations in long-term care for the growing numbers of the elderly, disabled and chronically ill. In FY 83, this program area encompassed studies of the populations in need of care, the factors affecting choice on different kinds of care, the effects of changes in public funding of services outside institutions, the economics of the long-term care industry, and methods to reimburse nursing homes prospectively. HCFA also funded demonstrations of community systems that help elderly clients obtain services and monitor the appropriateness of services.

National Channeling Demonstration

During FY 83, the 10 sites participating in the Department's National Channeling Demonstration continued to screen, assess, and serve clients determined to be at risk in institutional care. This demonstration was designed to investigate two channeling models: (1) a single entry community-based system of case management and assessment using existing health and social services (basic model), and (2) a single entry community-based system of case management and assessment with an array of services to be reimbursed by the Medicare/Medicaid programs (complex model). In addition to case management and assessment services, the five basic model sites, which are located in Maine, Maryland, Kentucky, Texas and New Jersey, were authorized to pay for a limited amount of gap-filling services.

Funds for additional noncovered Medicare and Medicaid services provided by the complex model sites come from a pooling of State and Federal monies based on a budget fixed at 60 percent of the costs that might be incurred if the demonstration population were treated in a nursing home. The complex model sites are located in New York, Massachusetts, Pennsylvania, Florida, and Ohio.

The evaluation contractor, Mathematica Policy Research, Inc., prepared a draft report describing in detail the channeling process at each site. They also continued to collect and edit data on the demonstration research sample (4,900 persons) and finalize the analysis plan. During FY 83, discussions took place between the Department and demonstration/evaluation participants regarding plans for an orderly phase out of the experiment (this phase out was scheduled to begin during FY 85).

National Hospice Demonstration

With the enactment of Medicare hospice legislation (September 1982) and the promulgation of regulations (November 1982), HCFA implemented its plans to wind-down the National Hospice Demonstration. On certification by Medicare, hospice organizations participating in the demonstration were permitted to receive reimbursement under the demonstration reimbursement methodology only for those Medicare beneficiaries enrolled prior to the date of certification. Payment for the cost of hospice services provided to other Medicare beneficiaries is made using the prospective payment methods prescribed by regulation. Reimbursement under the demonstration methodology for those patients enrolled prior to certification continued for a 6-month period.

AFDC Home Health Aide Demonstration

Section 966 of Public Law 96-499 authorized the Secretary to enter into agreements with States for the purpose of conducting demonstration projects to train and employ Aid to Families with Dependent Children (AFDC) recipients as homemakers and home health aides and to provide these services to elderly and disabled persons at risk of institutional care. In December 1981, HCFA selected seven States to participate in the demonstration. The seven States are Arkansas, Kentucky, New Jersey, New York, Ohio, South Carolina, and Texas.

During FY 83, the States implemented their plans to train AFDC recipients and provide services to individuals at risk of institutional care. In some of the participating States, the first group of home health aides trained under the demonstration ended their year of subsidized employment. Plans were developed in their respective States to help the aides make the transition to unsubsidized employment.

As specified by the legislation, the demonstration had a 6-month developmental period, 3 years of operation, and a 6-month phase-out period. Costs associated with the demonstration, including training and employment (up to 12 months) of the AFDC recipients, will be paid with 90 percent Federal funding under Title XIX of the Social Security Act.

Home Health Care Prospective Payment

During FY 83, HCFA undertook a research effort to develop and demonstrate alternative payment methods for home health services. In July 1983, HCFA issued a Request for Proposals to potential contractors to design and implement a demonstration to test several alternative methods of prospective payments for home health agencies (HHA's). The specific objectives are:

- o To determine the effect on Medicare and Medicaid expenditures of various methods of prospective payment.
- o To determine the effect of each payment mechanism on the availability and quality of home health care.
- o To determine the effect of each payment mechanism on HHA operations.

The project is carried out in three phases: Phase 1 involves the development of the specific payment methodologies to be tested, establishment of a research and design evaluation strategy, and the identification, selection and training of participating HHA's. Phase 2 involves the implementation of a 3-year demonstration, and Phase 3 will be the impact evaluation.

Competitive Bidding for Home Health Services

In a parallel effort on HHA reimbursement, HCFA started to develop a research strategy to test purchasing and payment methods that bring competitive market forces into the home health care field. Although HCFA's experience in the use of competition for specific health services is limited, the home health marketplace does contain elements that are important for testing competitive bidding (i.e., large number of providers, few barriers to entry, ability to compete on basis of quality or price). Through the use of a contractor, several models of competitive bidding for home health services under Medicare and Medicaid will be developed. The contractor will also develop a research design and implementation strategy and other deliverables that can be used by HCFA to test the competitive bidding models in a separate demonstration project under either Medicare, Medicaid, or both programs.

Alternative Family Care

During May 1983, the University of Washington was awarded a project to study the effects of providing training and respite care to families who are maintaining frail elderly family members at home. Under this demonstration, 600 patients (500 experimental and 100 control) are being studied to test the effectiveness of these services on the ability and willingness of families to retain primary responsibility for the care of aged members. The service phase of the project began in January 1984. The final evaluation is expected in 1987.

Nursing Home Case Mix

The New York State Department of Social Services was awarded a project effective August 7, 1983, to develop, test, and refine a long-term care prospective reimbursement system based on clusters of patient characteristics. This is being conducted by the New York State Department of Health and Rensselaer Polytechnic Institute. The system builds the results of research conducted at Yale University, which developed clusters of patients in relation to staff resources used (Resource Utilization Groups, RUG's). The purpose of the project is to promote efficiency by associating payment levels with patient characteristics which indicate the amount of actual services needed by patients. The State plans to implement the system developed under this project as New York's Medicaid payment system for nursing homes during 1986.

4. ALTERNATIVE PAYMENT SYSTEMS

Projects within this program area seek to improve the access of Medicare beneficiaries to health services, and at the same time, provide incentives to reduce the total cost of health care. Some studies explore alternative approaches to the organization and delivery of health care, while others modify payment methods of current health care institutions and practitioners.

In FY 83, HCFA implemented 35 Medicare Alternative Health Plan competition contracts. The majority of the contracts were with Health Maintenance Organizations (HMO's). More than 185,000 Medicare beneficiaries opted to leave the traditional Medicare program and join an alternative health plan. Because of the financial incentives offered through the prospective reimbursement provisions, the organizations were able to offer several additional benefits and monthly premiums that were less than equivalent values of coinsurance and deductibles.

The demonstrations indicated that alternative health plans will contract with HCFA to enroll Medicare beneficiaries if: (a) current reimbursement policies are modified to permit risk reimbursement; and (b) flexibility is granted that changes current reporting requirements. The success and lessons learned from the demonstrations aided in the development of regulations implementing the HMO provisions of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA).

5. PROGRAM ANALYSIS AND EVALUATION

HCFA maintains an active agenda of analyses to assess the impact of HCFA programs on the beneficiaries and to determine the extent to which our programs meet their goals. In our program analysis activities, data are collected and studied to analyze patterns and trends in the use of covered services and to measure the financial burden on the beneficiaries for medical care. Studies are designed to address these basic issues and to assess other issues important to the health of the beneficiaries, including access to needed care and the timely delivery of cost-effective and efficacious services.

Deductibles and Coinsurance

Liability for deductibles and coinsurance have an important impact on Medicare beneficiaries. Approximately 67 percent of Medicare beneficiaries purchase Medigap policies for protection against this liability. The Fall 1983 issue of the Health Care Financing Review reports the findings of a study which analyzed the distribution of beneficiaries by the amount of liability accrued during 1980. The study, "Options for Change under Medicare: Impact of a Cap on Catastrophic Illness Expense," also determined what surcharge beneficiaries could have paid to cover themselves for all liability above an arbitrary amount. The study found that only 21 percent of enrollees exceeded \$270 in liability from Part A and Part B combined. If every enrollee had paid a surcharge of about \$70, all liability over \$270 could have been capped. Projections for 1984 indicate that a surcharge of \$98 could cap all liabilities over \$800.

Medicare/Medicaid Entitlees

A subgroup of Medicare beneficiaries of special interest because of their higher rates of poverty and poorer health is the "crossovers," that is, enrollees entitled to both Medicare and Medicaid. In the summer 1983 issue of the Health Care Financing Review, an article entitled, "A Study of the 'Crossover Population': Aged Persons Entitled to both Medicare and Medicaid," appeared which analyzed the demographic characteristics, Medicare use, and mortality for the crossovers. The study found that the crossover population had a higher than average age, a higher proportion of persons of minority races, and a higher proportion of women than the general Medicare population. Crossovers had 1.6 times the average reimbursement per enrollee of other Medicare beneficiaries. Their age-adjusted mortality rates were 1.5 times that of other enrollees. The study discusses the interrelationship between Medicare and Medicaid and the role each plays in financing health care services for the elderly poor.

Health Maintenance Organizations

Another major area of study in ORD involves HCFA beneficiaries' enrollment in Health Maintenance Organizations (HMOs). HCFA initiated several demonstration projects to encourage HMOs to participate in the Medicare program under a risk payment mechanism mentioned previously. HCFA's payment mechanism is known as the Adjusted Average Per Capita Cost (AAPCC). The AAPCC adjusts the payment to HMOs for Medicare enrollees for five factors known to influence the level of Medicare outlays: age, sex, institutional status, welfare status, and county of residence. In 1983 a series of studies was underway, in coordination with the University Health Policy Consortium, Brandeis University, to determine if there are valid and reliable ways of refining the AAPCC. The research activities focused on three areas: (1) developing a model for including prior use in the computation of the AAPCC; (2) investigating the use of health status measures in the AAPCC; and (3) evaluating several methodological and statistical aspects of the AAPCC.

Preliminary results of these research efforts indicate that a model including prior use data available from routine Medicare administrative records may improve the accuracy of the AAPCC formula. In addition, an adjustment factor based on whether or not an aged enrollee was formerly entitled to Medicare under age 65 because of disability may also improve the accuracy of the AAPCC. The next step will be to test the prior use model in an HMO demonstration.

Surgical Hospitalizations

Two major studies on surgical hospitalization were begun in FY 1983. The first examines outcomes of surgery among Medicare enrollees for seven common operations. About 2.5 million hospital stays for surgery for Medicare enrollees occur annually. A substantial proportion of this surgery is discretionary to some degree. Thus, to the extent that some of these surgical procedures could be avoided, some of the associated mortality might be reduced. Using 1979-80 data, this study examines mortality up to a year after several common operations--cholecystectomy, prostatectomy, inguinal hernia repair, cataract removal, arthroplasty of the hip, reduction of fracture of the femur, and coronary bypass--comprising about one-quarter of operations for aged Medicare enrollees. A followup study will investigate the question of whether an association exists between mortality rates and annual volume of operations performed at individual hospitals. Another study will also describe the rehospitalization patterns of patients undergoing surgery.

Medicare Disabled

More research has been devoted to the Medicare aged population than to disabled enrollees. Yet disabled enrollees comprise about 10 percent of Medicare enrollment, and Medicare expenditures for them have been rising faster than for aged enrollees. A major study has been implemented to analyze patterns of health services used by the disabled. In particular, this population is being analyzed by type of disability award, i.e., disabled worker, adult disabled in childhood (ADC), or disabled spouse. Also, the aged (over 65 years of age) Medicare population who were formerly disabled Medicare beneficiaries are being studied.

Fixed Price Intermediary Contracts

An evaluation of Part B Fixed-Price Contracts was conducted by Abt Associates. This project is designed to evaluate the Medicaid Part B fixed-price carrier experiments in Maine, Illinois, and Upstate New York. The purpose of the study is to determine whether the fixed-price method will reduce Federal program costs through more efficient processing, while maintaining quality of carrier performance.

Inappropriate Hospital Utilization

In FY 1983, administrative initiatives were underway that will allow the Secretary to determine the medical necessity of inpatient hospital care and to make regional and national estimates of inappropriate hospital utilization.

There were two medical review methodologies being studied for this purpose: (1) the Appropriateness Evaluation protocol; and (2) the Standardized Medreview Instrument. The Appropriateness Evaluation Protocol (AEP) developed at Boston University was completed. The AEP is an instrument for determining appropriateness of hospital use. It is based on objective criteria items related to patient medical services, nursing and life support services, and patient condition. In addition, it contains a list of reasons for inappropriateness, structured to assist in identifying the causes of unnecessary admissions and days of care. The developers of the AEP have tested it and believe it to be a reliable and valid instrument that can be easily and economically applied in chart reviews by utilization review coordinators. (Gertman, P.M., and Restuccia, J.D., "The Appropriateness Evaluation Protocol: A Technique for Assessing Unnecessary Days of Hospital Care", Medical Care, 19:855-871, 1981).

Using the AEP instrument, these researchers compared inappropriate hospital use in four regions of the country. The study objectives were threefold: (1) to measure the amount of inappropriate (i.e., medically unnecessary) hospital admissions and days of care, (2) to identify the patient, hospital, and seasonal factors associated with inappropriate hospital use, and (3) to identify reasons for hospitalization in patients judged to be inappropriately hospitalized. AEP was retrospectively applied by trained nurse reviewers to a sample of 4,800 patient records to assess the appropriateness of hospital admissions and days of care.

Preliminary results indicated a substantial amount of inappropriateness as well as striking variations in the rates of inappropriateness for both hospital admissions and days of care. Overall, they found that the level of inappropriate admissions for Federal beneficiaries was 21 percent and the regional variation ranged from 13 percent to 31 percent. Cases judged to have inappropriate admissions were excluded from analyses of the factors associated with inappropriate days.

The other methodology being studied was the Standardized Medreview Instrument (SMI) which is intended to be a state-of-the-art medical review protocol that integrates the best of all major medical utilization review techniques. Following an extensive pretest of the instrument in 1981 in cooperation with the American Hospital Association (AHA) and an expert Technical Advisory Panel, a study of acute care hospitals involving primary data collection from 253 hospitals using (national) probability sampling techniques was conducted for the year 1981. The preliminary data analysis suggests a significantly lower rate of inappropriate admissions (on the order of 5-10 percent) than was found in earlier studies. The study population included all acute care non-Federal hospitals in the continental United States. Excluded were specialty hospitals, normal deliveries and pediatric patients. This study was unique in that it provided reliable estimates of the problem for the first time and included all classes of payors (commercial insurers, Blue Cross, self pay, and workmen's compensation) as opposed to merely Medicare and Medicaid patients usually studied and reported.

National Medical Expenditure Survey

During FY 1983, HCFA undertook joint planning with the National Center for Health Statistics (NCHS) and the National Center for Health Services Research (NCHSR) for the 1987 implementation of the National Medical Expenditure Survey (NMES). This survey will update the data collected in the 1977 National Medical Care Expenditure Survey (NMCES) and the 1980 National Medical Care Utilization and Expenditure Survey (NMCUES). The projected scope of NMES will exceed that of NMCES and NMCUES in that residents of nursing homes and facilities for the mentally retarded will be included. The two earlier surveys were limited to persons in households. Thus, NMES will provide a complete estimate of health services use and expenditures by the U.S. population as well as information on social economic characteristics including the sources of payment for health care services. It will address issues of the medical services used by specified sectors of the HCFA beneficiary population in households (e.g., Hispanics, Blacks, the aged, and welfare recipients) as well as the long-term care services used by the aged and the mentally retarded, two principal consumer groups of long-term care benefits under Medicaid. Reports for future years will provide additional details concerning the planning for NMES.

During FY 83, ORD was responsible for assessing the effectiveness of specific national program or policies. Major evaluations are mandated by Congress, initiated by the Secretary, or determined by administrative initiative. In this Program Evaluation segment, we discuss ORD's responsibility for three congressionally mandated studies related to Medicare: (1) the Hospital Providers of Extended Care Services (Rural Swing-Bed) Evaluation; (2) the Voluntary Certification of Medicare Supplemental Health Insurance Policies (Medigap certification/penalties) Evaluation; and (3) End-Stage Renal Disease evaluative studies. Administrative initiatives are in progress for estimation of inappropriate hospital utilization.

Swing-Bed

Congress mandated an evaluation of the impact of the rural swing-bed program. The evaluation includes analyses of the program's impact on access to and use of long-term care services in rural areas with shortages of nursing home beds. This project assesses whether such services furnished in small (less than 50 beds) rural hospitals are cost effective and comparable in quality to the services furnished in certified nursing home facilities. The report's findings will assist in determining whether eligibility to participate in the swing-bed program should be extended to other hospitals, regardless of bed size or geographic location, when there is a shortage of long-term care beds. Findings consistent with earlier demonstration experiences would validate expectations that the swing-bed program could assist rural communities in meeting both long-term care and acute care needs. In the course of examining the impact of the swing-bed program, it is expected that many aspects of the effects of instituting the prospective payment system in hospitals will become apparent.

Medigap

In FY 83, ORD was also engaged in a congressionally mandated study of the possible "Medigap problem." The purpose of this study is to ascertain the effectiveness of State insurance regulations, permitting more informed choice, reducing duplicative coverage, and limiting marketing abuses. A survey of Medicare beneficiaries and of insurance companies was conducted in six States: California, Florida, Mississippi, New Jersey, Washington, and Wisconsin. A Medigap Advisory Panel was formed with 10 representatives from State and Federal regulatory authorities, the insurance industry, and consumer and aging organizations. The panel met to review the consumer survey draft reports in June 1983. The report found that three State actions appear to result in the purchase of higher quality policies. They are:

- o Establishing minimum benefit requirements.
- o Setting minimum loss ratios.
- o Distributing consumer guides.

Although State regulations seem to have less impact on sales abuse, two strategies--distributing consumer guides, and issuing press releases when companies or agents are found guilty of misrepresentation--appear to have some beneficial effect.

Finally, the distribution of consumer guides was associated with greater consumer knowledge of Medicare or the policies purchased. The final report of the consumer survey is completed.

The Medigap legislation further requires ongoing evaluations of the effect of the certification and criminal penalties provisions. A descriptive report on the Medigap certification process is included as a separate section of this report. Subsequent biennial Medigap evaluation reports will include analyses of the impact of the program and penalties on the type, market share, value, and cost to individuals entitled to benefits of Medigap policies certified by the Secretary.

End-Stage Renal Disease

ORD has a broad-ranging research, demonstration and evaluation program in the area of End-Stage Renal Disease (ESRD). Information about these activities is included in the detailed ESRD section of this report. (See Page)

6. COVERAGE

In FY 1983, research, demonstration, and evaluation projects assessed the costs and benefits of expanding Medicare and Medicaid coverage to include new benefits or providers, to consider alternative methods of providing the benefits under study, and to address the effects of these alternatives on beneficiaries.

Initiatives were underway in the area of expanding ambulatory service coverage to Medicare beneficiaries:--alcoholism, mental health services, and urban health clinics services, for ESRD and heart transplants.

Both the alcoholism services and mental health services demonstrations are aimed at testing the cost-effectiveness of providing Medicare and/or Medicaid coverage for mental health services provided in ambulatory centers that currently do not have provider status. The hypothesis in both projects is that services can be provided effectively and efficiently at less cost in these settings than in traditional hospital inpatient or outpatient treatment settings. The mental health services demonstration was completed in April 1983. The alcoholism service demonstration is not scheduled to be completed until 1985.

HCFA initiated its urban health clinics demonstration which examines the relative advantages and disadvantages of reimbursement on the basis of costs and fee-for-service for physician-directed clinics employing physician assistants or nurse practitioners. These clinics are located in medically underserved areas in two States, Tennessee and California, and services are paid for under the demonstration until 1985. One demonstration issue is whether urban health clinics staffed with physician extenders may provide services in a more cost-effective manner. The evaluation is being conducted by A.D. Little, Inc., of Cambridge, Massachusetts and will be completed in August 1986.

HCFA and the Robert Wood Johnson Foundation continued to support demonstrations to determine whether primary care clinics affiliated with municipal outpatient departments could improve access to care and contain costs in urban areas. Twenty clinics in five cities are currently providing routine and ancillary services in this demonstration. In the aggregate, ancillary charges have been highest for dentistry and dentures, followed by pharmacy. Four of the five participating cities have attained the Robert Wood Johnson Foundation criteria for success: their Municipal Health Services Project (MHSP) clinic costs per visit are two-thirds or less of the cost per visit for that city's municipal hospital outpatient department and emergency room services. In addition, it was originally hypothesized that the improved access to primary care clinics would result in a decrease in the MHSP users' total cost and utilization of all inpatient and emergency room services. From preliminary results, it appears this hypothesis is true in four of the cities.

HCFA has sponsored three demonstrations which changed ESRD benefits by extending coverage to the services of a dialysis aide for maintenance dialysis sessions performed in the patients' homes. The primary purpose was to test whether or not providing this extra benefit resulted in more patients choosing home dialysis as a treatment option. In addition, the impact on cost and quality of care were documented for analysis.

The evaluators summarized their findings as follows:

- o The cost of dialysis in the home setting was less than two-thirds the maintenance dialysis cost in the facility setting when the experimental provision of aide payment was excluded from the calculation. When aide payments were included, the cost of the home setting was just over 70 percent of the cost of facility dialysis.
- o The proportion of home-based patients in the paid aide experimental group increased approximately 5 percent while the proportion of home-based patients in the control group decreased approximately 2 percent during the demonstration.
- o There appeared to be little or no differences between hospital-based and free-standing facilities in the demographic and medical characteristics of hemodialysis patients.
- o Home-based hemodialysis patients were found to be generally younger, in better physical condition, and have higher personal and family income levels than facility-based patients.
- o Fewer home-based hemodialysis patients experienced changes in marital status (divorce and separation) than facility-based patients. Both patient groups experienced increases in unemployment rates after the initiation of dialysis treatments. Changes in marital and employment status were generally attributed by patients to be a result of renal disease and the requirements of dialysis.

HCFA awarded a project to the Urban Institute to explore different approaches for testing competitive financing approaches in the ESRD program. The possibilities include competitive bidding; capitation covering all medical care cost as well as other options with coverage limited to outpatient ESRD services; and voucher payments allowing patients to share in the financial savings of cost-reducing shifts. A final report is expected in FY 1986.

A "National Heart Transplantation Study" was carried out by the Battelle Human Affairs Research Center in Seattle. This project is designed to evaluate the scientific, economic, ethical, legal, and social factors related to heart transplantation. It includes the collection and analysis of data on organ procurement, need for transplantation, costs, and survival of transplant patients. This project began in September 1981, and data collection was underway in FY 1983 with a report expected in FY 1985.

DATA BASE AND STATISTICAL ACTIVITIES

The central administration of the Medicare program at the Federal level has permitted the development of a uniform multipurpose Medicare data base that serves the needs of planners, researchers, and policymakers. HCFA uses this claims-based statistical system, together with other reporting systems, to prepare a wide variety of statistical and analytical reports and studies on the utilization and reimbursement of health care services financed by Medicare

and Medicaid. To improve the accessibility of the data, the Medicare Automated Data Retrieval System (MADRS) is designed to organize the Medicare bill and payment records by year, geographic region (county), and health insurance claim number. This will allow quick retrieval of data for research and demonstration studies.

HCFA maintains a statistical program to generate information on the ongoing operation of the Medicare and Medicaid programs. Program statistical reports are issued on a regular basis that provide data on the number and characteristics of program beneficiaries; the number, distribution, and characteristics of providers certified to furnish services to Medicare beneficiaries; and the patterns of use of program benefits by beneficiaries. Use of benefits is examined by the characteristics of the persons using them, the providers furnishing the services, and the distribution of charges and reimbursements to beneficiaries and providers. The purpose of these reports is to show trends and to examine the factors that may be influencing those trends.

Because of the limitations in existing statistical reports for the Medicaid program, ORD began a project in 1981 to develop a new source of Medicaid data at the Federal level. This pilot project, known as "Tape-to-Tape," has acquired detailed data on enrollment, use of services, expenditures, and providers from individual State Medicaid Management Information Systems. Since these data lack uniformity across the States, one of the project's primary goal has been to develop uniform data sets for the participating States. By the end of 1983, five States (California, Georgia, Michigan, New York, and Tennessee) had agreed to provide Medicaid data for the years 1980 through 1982. This data will provide HCFA with greater capability to conduct program evaluation, strengthen program management, and evaluate policy alternatives for the Medicaid program. In addition, plans were made to link these data with data from the Medicare program in order to study the total range of health care services that are provided to persons who are enrolled under both the Medicare and Medicaid programs.

The Medicare and Medicaid Data Book, 1983, presents comprehensive annual program data describing the Medicare and Medicaid programs. The report is intended to serve as a resource tool for public officials, researchers, policy analysts, and consumers who have an interest in these health programs. It features analyses on recent trends in program beneficiaries, expenditures, and service utilization, as well as in-depth discussions of the basic operating principles of each program.

Other ongoing statistical studies continued to better document access and use of Medicare services. This included selected highlight notes which provide a brief and timely summary on the use and cost of services for each of the major Medicare program benefits (e.g., short-stay and long-stay hospital, skilled nursing care, home health agency, hospital outpatient, etc).

Statistical studies were also undertaken to examine areas of special interest regarding policy and legislative initiatives affecting the health care community. For example, one study discussed utilization and charge patterns for those

Medicare beneficiaries discharged from short-stay hospitals with the principal diagnosis of diabetes. Another study provided similar data for beneficiaries with a principal diagnosis of cataracts. These studies provided the following highlights:

- o The annual discharge rate per 1,000 aged hospital insurance (HI) enrollees with diabetes ranged from 5.6 in the West to 9.2 in the North Central region, a difference of 64 percent.
- o Among the aged with cataracts, the annual rate per 1,000 HI enrollees ranged from 10.4 in both the Northeast and North Central regions to 11.9 in the South.

A HCFA program statistical report on the availability and access to Medicare providers and suppliers of services showed the following significant variation by geographic area:

- o The number of Medicare certified short-stay hospital beds per 1,000 HI enrollees ranged from 31 in the New England States to 42 in the West South Central States. Certified skilled nursing facility beds per 1,000 HI enrollees ranged from 2 in the West South Central States to 28 in the Pacific States.
- o Among the 50 States, 19 had more than 100 HHA's and 9 States, including the District of Columbia, had 15 or fewer agencies approved by Medicare.
- o Of the independent laboratories certified by Medicare, 33 percent of the laboratories were located in California, Texas, and New York.

A data base that was fully implemented in FY 80 is derived from the Medicare statistical system. Through linkage of Medicare eligibility and claims files, a continuous history sample of 5 percent of all Medicare beneficiaries links their use of Medicare benefits beginning with benefits received in 1974.

Work progressed on projects to link this continuous history sample to other data bases outside HCFA to expand the range of analyses possible on Medicare beneficiaries. The Medicare history file was linked to mortality data from the National Center for Health Statistics and to disability award data from the Social Security Administration. These linked files permit studies of the relation of Medicare use to mortality and disability variables.

In addition to reports based on the Medicare and Medicaid claims payment systems, HCFA planned a series of reports from the National Medical Care Utilization and Expenditure Survey (NMCUES) of 1980. NMCUES collected detailed sociodemographic, health status, health insurance, and health care payment data that were not available from either the Medicare or Medicaid administrative record systems. The data will allow for analysis of policy issues relating to out-of-pocket costs, access to health care, and Medicaid use by social and ethnic groups.

Two reports on aged Medicare beneficiaries, concerning their health status and access to medical care, were among the early reports prepared. The NMCUES questionnaires and accompanying procedures were published in early 1983.

The Office of the Actuary maintains a data base on national health spending by sector of care, and by source of payment. The Health Care Financing Review reported trends in spending and sources of payment through calendar year 1983 and in the winter of 1984 issue.

Revised data for calendar year 1983 and estimates of national health expenditures in 1984 are included in the forthcoming Fall 1985 issue of the Health Care Financing Review.

Projections of national health spending by sector and by source of payment through 1990 appear in the Spring 1984 issue of the Health Care Financing Review. The most recent article projected that National Health Expenditures could reach \$660 billion in 1990, or 11.3 percent of the Gross National Product. The national health expenditure data base also include distributions of health spending and sources of payment by age group, with special emphasis on persons age 65 and older, and by State.

HCFA RESEARCH PUBLICATIONS PROGRAM

HCFA continued its research publications program in FY 83 while conforming to the guidelines of the moratorium on government publications. A series of color-keyed publications that cover research and demonstration activities as well as statistical information on the Medicare program are part of a dissemination effort to reach interested user groups and provide research results for policymakers and health professionals.

HCFA publishes the following series that include information on Medicare:

- o Health Care Financing Review is a quarterly research journal that carries articles relating to the Medicare program.
- o Health Care Financing Program Statistics contain detailed data and analyses on the Medicare program. Included are Medicare data on enrollment, providers, and use of and reimbursement for covered services.
- o Health Care Financing Grants and Contracts Reports present the final reports from selected HCFA-funded extramural projects of the kind described in this chapter.
- o Health Care Financing Research Reports present the results of major studies and projects conducted by HCFA program staff.
- o Health Care Financing Notes provide descriptive data on selected aspects of the Medicare program in a brief format.
- o Health Care Financing Monographs include publications that do not fit into the other series. Examples include a brochure on the grants program, conference proceedings, and a report that briefly describes all ongoing intramural and extramural projects conducted by the Office of Research and Demonstrations, "Research and Demonstrations in Health Care Financing."

Additional information on the research publications program and the availability of various reports may be obtained from ORD Publications, Room 1-A-9 Oak Meadows Building, 6325 Security Boulevard, Baltimore, Md. 21207.

APPENDIX A

Part A Intermediaries and Part A Blue Cross Plans

PART A - INTERMEDIARIES

Blue Cross and Blue Shield Association
676 North St. Clair Street
Chicago, IL. 60611

Aetna Life Insurance Company
151 Farmington Avenue
Hartford, CT 06156

Cooperative de Seguros
de Vida Puerto Rico
Post Office Box 3428 G.P.O.
San Juan, PR 00936

Hawaii Medical Service Association
1504 Kapiolani Boulevard
Post Office box 860
Honolulu, HI 96808

Mutual of Omaha Insurance Company
Post Office Box 456
Downtown Station
Omaha, NE 68101

The Prudential Insurance Company
of America
Drawer 471
Millville, NJ 08332

The Travelers Insurance Company
One Tower Square
Hartford, CT 06115

PART A - BLUE CROSS PLANS

Blue Cross of Alabama
450 Riverchase Parkway East
Birmingham, Alabama 35298

Blue Cross and Blue Shield
of Arizona, Inc.
321 West Indian School Road
Post Office Box 13466
Phoenix, AZ. 85002

Arkansas Blue Cross and Blue
Shield, Inc.
601 Gaines Street
Little Rock, AR 72203

Blue Cross of California
Post Office Box 70000
Van Nuys, CA 91470

Blue Cross and Blue Shield
of Colorado
700 Broadway
Denver, CO 80273

Blue Cross and Blue Shield
of Connecticut, Inc.
370 Bassett Road
North Haven, CT 06473

Blue Cross and Blue Shield
of Delaware, Inc.
201 West 14th Street
Wilmington, DE 19899

Group Hospitalization, Inc.
550 12th Street, SW
Washington, DC 20024

Blue Cross of Florida, Inc.
Post Office Box 1798
Jacksonville, FL 32201

PART A - BLUE CROSS PLANS

Blue Cross and Blue Shield
of Georgia/Atlanta, Inc.
3348 Peachtree Road, NE
Post Office Box 4445
Atlanta, GA 30302

Blue Cross of Georgia/Columbus, Inc.
2357 Warm Springs Road
Post Office Box 7368
Columbus, GA 31908

Blue Cross of Idaho Health
Service, Inc.
1501 Federal Way
Post Office Box 7408
Boise, ID 83707

Health Care Service Corporation
233 North Michigan Avenue
Chicago, IL 60601

Mutual Hospital Insurance, Inc.
120 West Market Street
Indianapolis, IN 46204

Blue Cross of Iowa
Ruan Building
636 Grand Avenue
Des Moines, IA 50307

Blue Cross of Western Iowa
and South Dakota
Third and Pierce Streets
Sioux City, IA 51102

Blue Cross of Kansas, Inc.
1133 Topeka Boulevard
Post Office Box 239
Topeka, KS 66601

Blue Cross and Blue Shield
of Kentucky, Inc.
9901 Linn Station
Louisville, KY 40223

Louisiana Health Service
and Indemnity Company
Post Office Box 15699
Baton Rouge, LA 70895

Associated Hospital Service
of Maine
110 Free Street
Portland, ME 04101

Blue Cross of Maryland, Inc.
700 East Joppa Road
Towson, MD 21204

Blue Cross of Massachusetts, Inc.
100 Summer Street
Boston, MA 02106

Blue Cross and Blue Shield
of Michigan
600 Lafayette East
Detroit, MI 48226

Blue Cross and Blue Shield
of Minnesota
3535 Blue Cross Road
St. Paul, MN 55765

Blue Cross and Blue Shield
of Mississippi, Inc.
Post Office Box 1043
Jackson, MS 39205

Blue Cross Hospital Service, Inc.
of Missouri
4444 Forest Park
St. Louis, MO 63108

Blue Cross of Montana
3360 10th Avenue, South
Post Office Box 5017
Great Falls, MT 59403

Blue Cross and Blue Shield
of Nebraska
Post Office Box 3248
Main Post Office Station
Omaha, NE 68103

New Hampshire-Vermont Health
Service
Two Pillsbury Street
Concord, NH 03306

PART A - BLUE CROSS PLANS

Hospital Service Plan
of New Jersey
33 Washington Street
Newark, NJ 07102

New Mexico Blue Cross
and Blue Shield, Inc.
12800 Indiana School Road, NE
Albuquerque, NM 87112

Blue Cross and Blue Shield
of Greater New York
622 Third Street
New York, New York 10017

Blue Cross and Blue Shield
of North Carolina
Post Office Box 2291
Durham, NC 27702

Blue Cross of North Dakota
4510 13th Avenue, SW
Fargo, ND 58121

Hospital Care Corporation
1351 William Howard Taft Road
Cincinnati, OH 45206

Blue Cross of Northeast Ohio
2066 East Ninth Street
Cleveland, OH 44115

Blue Cross of Central Ohio
255 East Main
Post Office Box 16526
Columbus, OH 43216

Blue Cross of Northwest Ohio
Post Office Box 943
Toledo, OH 43656

Blue Cross and Blue Shield
of Oklahoma
1215 South Boulder Avenue
Tulsa, OK 74119

Northwest Hospital Service
100 SW Market Street
Post Office Box 1217
Portland, OR 97201

Hospital Services Plan
of the Lehigh Valley
1221 Hamilton Street
Allentown, PA 18102

Capital Blue Cross
100 Pine Street
Harrisburg, PA 17101

Blue Cross of Greater Philadelphia
1333 Chestnut Street
Philadelphia, PA 19107

Blue Cross of Western Pennsylvania
One Smithfield Street
Pittsburgh, PA 15222

Hospital Service Association
of Northeastern Pennsylvania
Blue Cross Building
70 North Main Street
Wilkes-Barre, PA 18711

Blue Cross of Rhode Island
444 Westminster Mall
Providence, RI 02901

Blue Cross and Blue Shield
of South Carolina
Drawer F. Forest Acres Branch
Columbia, SC 29260

Blue Cross and Blue Shield
of Tennessee
Blue Cross Building
Chattanooga, TN 37402

Group Hospital Service, Inc.
Post Office Box 222146
Dallas, TX 75222

Blue Cross of Utah
2455 Parleys Way
Post Office Box 30270
Salt Lake City, UT 84125

Blue Cross of Virginia
2015 Staples Mill Road
Post Office Box 27401
Richmond, VA 23279

Blue Cross of Southwestern
Virginia
Post Office Box 13047
3959 Electric Road
Roanoke, VA 24045

Blue Cross of Washington
and Alaska, Inc.
15700 Dayton Avenue, Inc.
Post Office Box 327
Seattle, WA 98111

Blue Cross Hospital Service, Inc.
Post Office Box 1353
Commerce Square
Charleston, WV 25325

Associated Hospital Service, Inc.
401 West Michigan Street
Post Office Box 2025
Milwaukee, WI 53203

Blue Cross Blue Shield
of Wyoming
4000 House Avenue
Post Office Box 2266
Cheyenne, WY 82001

APPENDIX B

Part B - Blue Shield Plans

Part B - Commercial, Other

PART B - BLUE SHIELD PLANS

Blue Cross and Blue Shield
of Alabama
450 Riverchase Parkway, East
Birmingham, AL 35298

Arkansas Blue Cross and
Blue Shield, Inc.
601 Gaines Street
Little Rock, AK 72203

California Physicians Service
2 Northpoint Street
Post Office Box 7968-Rincon Annex
San Francisco, CA 94120

Blue Cross and Blue Shield
of Colorado
700 Broadway
Denver, CO 80273

Blue Shield of Florida, Inc.
Post Office Box 1798
Jacksonville, FL 32231

Mutual Medical Insurance, Inc.
120 West Market Street
Indianapolis, IN 46204

Blue Shield of Iowa
Ruan Building
636 Grand Avenue
Des Moines, IA 50307

Blue Shield of Kansas, Inc.
113 Topeka Boulevard
Post Office Box 239
Topeka, KS 66601

Blue Shield of Kentucky
9901 Linn Station Road
Louisville, KY 40223

Blue Shield of Maryland, Inc.
700 East Joppa Road
Towson, MD 21204

Blue Shield of Massachusetts, Inc.
100 Summer Sreet
Boston, MA 02106

Blue Cross and Blue Shield
of Michigan
600 Lafayette East
Detroit, MI 48226

Blue Shield of Minnesota
3535 Blue Cross Road
St. Paul, MN 55765

Blue Shield of Kansas City
Post Office Box 169
Kansas City, MO 64141

Montana Physicians Service
404 Fuller Avenue
Post Office Box 4310
Helena, MT 59601

New Hampshire-Vermont Health
Service
Two Pillsbury Street
Concord, NH 03306

Blue Shield of Western
New York, Inc.
15 Chenango Street
Binghamton, NY 13901

Blue Cross and Blue Shield
of Greater New York
622 Third Avenue
New York, NY 10017

Blue Shield of North Dakota
4510 13th Avenue, SW
Fargo, ND 58121

Pennsylvania Blue Shield
Post Office Box 65
Camp Hill, PA 17011

Seguros de Servicio de Salud
de Puerto Rico, Inc.
Post Office Box 3628 G.P.O.
San Juan, PR 00936

Blue Shield of Rhode Island
444 Westminster Mall
Providence, RI 02901

Blue Cross and Blue Shield
of South Carolina
Drawer F, Forest Acres Branch
Columbia, SC 29219

Group Medical and Surgical Service
Post Office Box 222147
Dallas, TX 75222
2455 Parleys Way
Post Office Box 30270
Salt Lake City, UT 84125

Washington Physicians Service
2401 4th Avenue
4th and Battery Building
6th Floor
Seattle, WA 98121

Wisconsin Physicians Service
Insurance Corporation
Post Office box 9277
Madison, WI 53715

PART B - COMMERCIALS, OTHER

Aetna Life Insurance Company
151 Farmington Avenue
Hartford, CT 06156

Connecticut General Life
Insurance Company
900 Cottage Grove Road
Hartford, CT 06152

E.D.S. Federal Corporation
7171 Forest Lane
Dallas, TX 75230

The Equitable Life Assurance
Society of the United States
1285 Avenue of the Americas
New York, NY 10019

General American Life Insurance
Company
Post Office Box 505
St. Louis County, MO 63166

Group Health Incorporated
326 West 42nd Street
New York, NY 10036

Mutual of Omaha Insurance
Company
Post Office box 456
Downtown Station
Omaha, NE 68101

Blue Shield of Utah
Nationwide Mutual Insurance Company
Post Office Box 1625
Columbus, OH 43216

Transamerica Occidental Life
Insurance Company
Post Office Box 54905, Terminal Annex
12th at Hill Street
Los Angeles, CA 90054

Pan-American Life Insurance
Company
Post Office Box 60450
New Orleans, LA 70160

The Prudential Insurance
Company of America
Drawer 471
Millville, NJ 08332

The Travelers Insurance Company
One Tower Square
Hartford, CT 06115

State of Residence	Beneficiaries (7-1-83) ^{1/}		Benefit Payments (FY83)	
	Hospital	Medical	Hospital	Medical
	Insurance	Insurance	Insurance	Insurance
	(in millions)			
Total, All Areas ^{2/}	29,587,295	28,974,535	\$38,102 ^{3/}	\$17,487 ^{3/}
Alabama	503,284	501,019	625	239
Alaska	15,243	13,785	24	10
Arizona	369,773	361,901	383	236
Arkansas	353,589	350,883	344	184
California	2,732,586	2,728,113	4,153	2,377
Colorado	285,019	280,537	352	180
Connecticut	416,142	412,911	515	252
Delaware	71,585	70,338	82	45
District of Columbia	73,337	72,060	154	74
Florida	1,850,395	1,847,685	2,416	1,386
Georgia	610,557	610,367	638	318
Hawaii	90,772	89,677	97	57
Idaho	111,937	109,529	102	47
Illinois	1,389,686	1,376,008	2,186	758
Indiana	673,474	662,490	858	309
Iowa	426,815	422,487	496	176
Kansas	333,700	329,689	456	173
Kentucky	472,661	471,295	505	181
Louisiana	453,831	432,665	537	182
Maine	163,221	161,700	200	77
Maryland	447,953	439,786	687	302
Massachusetts	797,421	784,970	1,235	537
Michigan	1,083,130	1,072,789	1,627	805
Minnesota	532,277	526,735	631	247
Mississippi	327,146	327,307	355	141
Missouri	718,808	708,144	1,045	305
Montana	100,513	98,839	104	47
Nebraska	223,503	220,475	253	93
Nevada	86,894	85,061	132	68
New Hampshire	119,018	116,781	135	57
New Jersey	980,205	976,316	1,295	671
New Mexico	138,713	136,498	148	78
New York	2,359,039	2,341,848	3,298	1,673
North Carolina	722,771	718,743	713	307
North Dakota	90,361	89,091	122	45
Ohio	1,349,137	1,333,751	1,853	715
Oklahoma	404,700	400,613	496	186
Oregon	355,035	344,124	433	171
Pennsylvania	1,749,889	1,728,449	2,467	1,111
Rhode Island	143,649	141,820	182	95
South Carolina	351,167	348,263	349	150
South Dakota	100,704	99,106	117	40
Tennessee	597,735	595,824	677	267
Texas	1,509,160	1,503,455	1,966	949
Utah	128,591	124,174	115	59
Vermont	67,113	66,410	80	31
Virginia	593,582	582,807	662	295
Washington	502,565	492,330	513	259
West Virginia	280,448	278,094	319	108
Wisconsin	644,115	638,427	795	311
Wyoming	43,457	42,295	49	19
Puerto Rico	377,276	233,745	104	66
Virgin Islands	5,388	5,018	3	1
Other Areas ^{4/}	3,168	2,676	2	1

^{1/} Represents persons enrolled for coverage, by program as of July 1, 1983.

^{2/} Included in All Areas but not shown separately are data for beneficiaries residing in foreign countries and beneficiaries whose State of Residence is currently unknown.

^{3/} Benefit payments for All Areas represent actual trust fund disbursements excluding administrative expenses. Distribution of benefit payments by geographic area was estimated based on interim reimbursements in CY 1982 as reflected on bills recorded in central office. Payments reflect residence of beneficiary. Benefit payments are shown in millions of dollars. Detail may not sum to total due to rounding.

^{4/} Other Areas includes data for Guam, American Samoa, and other outlying areas.

Appendix D

Five-Year Trend Analysis for Contractor Administrative Costs and Productivity Improvements

PART A INTERMEDIARIES

FY 1979 Through FY 1983

The following tables contain significant workload, administrative cost, average manpower, and benefit payment data reflecting the combined performance of all Part A intermediaries from Fiscal Year 1978 through 1982.

During this period, the annual workloads rose a total of 30.7 percent over the base, while total administrative costs rose only 21.3 percent. In terms of total unit cost, the decrease from \$5.49 to \$5.09 is 7.3 percent. These decreased costs reflect the expanded use of automatic data processing equipment, improved procedures, and the implementation of fixed price contracts.

PART A INTERMEDIARIES TREND DATA AND INDICES WORKLOAD AND COST

<u>FY</u>	<u>Bills Processed</u>	<u>Total Adm. Cost</u>	<u>Total Unit Cost</u>	<u>Admin. Cost</u>	<u>Unit Cost Ex. Audit</u>	<u>Provider Audit and Reimbursement</u>
79	36,410,000	\$201,546,200	\$5.54	\$147,411,000	\$4.05	\$51,980,900
80	39,789,300	\$216,037,000	\$5.43	\$155,131,500	\$3.90	\$60,905,500
81	42,539,800	\$234,615,400	\$5.52	\$166,190,200	\$3.91	\$68,425,300
82	45,551,700	\$231,930,900	\$5.09	\$162,468,100	\$3.57	\$69,462,800
83	48,688,900	\$261,824,200	\$5.38	\$173,830,400	\$3.57	\$87,993,831
INDICES (FY 79 AS 100 PERCENT)						
79	100.0	100.0	100.0	100.0	100.0	100.0
80	109.2	107.1	98.0	105.2	96.3	117.2
81	116.8	116.4	99.6	112.7	96.5	131.6
82	125.1	115.0	91.8	110.2	88.1	133.6
83	133.7	129.9	97.1	117.9	98.1	169.3

Appendix D (con't)

PART A INTERMEDIARIES
TREND DATA AND INDICES
PRODUCTIVITY, PERSONAL SERVICE COSTS, AND BENEFITS

<u>FY</u>	<u>Staff Years</u>	<u>Productivity Per Staff Year</u>	<u>Average PS Cost Per Staff year</u>	<u>Benefits Paid (M)</u>	<u>Benefits Paid Per Bill</u>	<u>Percent Administrative Cost to Beneficiary (Including Audit)</u>
79	6,681.0	5,450	\$15,623	\$20,931,400	\$574.88	1.0
80	6,211.6	6,406	\$17,121	\$25,238,000	\$634.29	0.9
81	5,819.5	6,862	\$18,157	\$30,703,700	\$721.76	0.8
82	4,459.7	9,008	\$21,263	\$36,590,600	\$803.28	0.6
83	4,289.2	9,911	\$23,185	\$40,207,500	\$825.80	0.7
INDICES (FY 1979 AS 100 PERCENT)						
79	100.0	100.0	100.0	100.0	100.0	100.0
80	93.0	117.5	109.6	120.6	110.3	90.0
81	87.1	125.9	116.2	146.7	125.5	80.0
82	66.8	165.3	136.1	174.8	139.7	60.0
83	64.3	181.9	148.4	192.1	143.6	70.0

Appendix D (con't)

PART B CARRIERS

FY 1979 Through FY 1983

The following tables contain significant workload, administrative cost, average manpower, and benefit payment data reflecting the combined performance of all Part B carriers from fiscal year 1979 through 1983.

During the period, the annual workload rose a total of 52.9 percent over the base, while total administrative costs rose only 33.2 percent. In terms of unit cost for processing claims, the decrease from \$2.81 to \$2.38 is 15.3 percent. Contributing to the reduced cost of processing a claim, in addition to expanded use of data processing equipment and improved procedures, are the increased use of facilities management subcontracts and fixed price contracts.

**PART B CARRIERS
TREND DATA AND INDICES**

Workload and Cost

<u>FY</u>	<u>Claims Processed</u>	<u>Administrative Cost</u>	<u>Claims Unit Cost</u>	<u>Payment Received Processed</u>	<u>Payment Received Unit Cost</u>
79	133,494,900	\$375,273,500	\$2.81	112,864,600	\$3.32
80	152,312,600	\$389,043,300	\$2.61	129,465,800	\$3.07
81	169,541,700	\$450,537,700	\$2.66	148,529,800	\$3.03
82	185,769,600	\$458,819,500	\$2.47	158,994,200	\$2.89
83	204,048,800	\$485,833,300	\$2.38	167,498,800	\$2.90

Indices

79	100.0	100.0
80	114.1	92.5
81	127.0	91.3
82	139.2	87.0
83	152.9	87.3

Appendix D (con't)

PRODUCTIVITY, PERSONAL SERVICE COST, AND BENEFITS
EXCLUDING PSRO AND HMO

<u>FY</u>	<u>Staff Years</u>	<u>Productivity Per Staff Year</u>	<u>Average PS Cost Per Staff Year</u>	<u>Benefits Paid (M)</u>	<u>Benefits Paid Per Bill</u>	<u>Percent Admin- istrative Cost to Beneficiary</u>
79	16,474.0	8,103	\$13,753	\$6,360,065	\$47.64	5.9
80	15,514.9	9,817	\$15,172	\$7,798,407	\$51.20	5.1
81	15,523.8	10,293	\$16,601	\$9,388,767	\$55.38	4.8
82	13,202.9	13,247	\$18,677	\$11,186,164	\$60.20	4.1
83	12,985.7	15,132	\$20,151	\$13,674,657	\$67.02	3.6

INDICES (FY 1979 AS 100 PERCENT)

79	100.0	100.0	100.0	100.0	100.0	100.0
80	94.2	121.2	110.3	122.6	107.5	86.4
81	94.2	127.0	120.7	147.6	116.2	81.4
82	80.1	163.5	135.8	175.9	126.4	69.5
83	78.8	186.7	146.5	215.0	140.7	61.0

APPENDIX E

SIGNIFICANT LEGISLATION ENACTED DURING FY 1983

P.L. 97-414 - The Orphan Drug Act

Enactment date: January 4, 1983

Section 6 of the Orphan Drug Act, H.R. 5238, requires HHS to submit to Congress several reports on home health services. These reports are to provide:

- o Data on the impact of previous grants and contracts, the need to continue grants and loans under the new Act, and the extent to which standards have been applied to training of personnel who provide home health services. Due date: January 1, 1984.
- o The results of recent studies evaluating home-and community-based services and any recommendations for legislative changes which might improve the provision of such services. Due date: Prior to January 1, 1985.
- o An analysis of the results of significant studies conducted by any public or private entity on alternative reimbursement methodologies for home health services. The report must contain recommendations as to how such methodologies might be applied to federally funded programs. Due date: Within six months after enactment.
- o The results of demonstrations testing: (1) methods for identifying patients at risk of institutionalization who could be treated more cost-effectively in a home health program, including hospitalized Medicare patients who are candidates for early discharge due to availability of home health services, and persons in the community who could avoid institutionalization if they had access to home health services; and (2) alternative reimbursement methodologies for home health agencies to determine the most cost-effective and efficient way of providing home health services, including fee schedules, prospective reimbursement, and capitation payments. Due date: The demonstrations are to commence no later than January 1, 1984, and a report on the findings is due to Congress no later than January 1, 1985.

P.L. 97-448 - The Technical Corrections Act of 1982

Enactment date: January 12, 1983

Section 309 of the Technical Corrections Act of 1982, H.R. 6056, makes a number of technical and minor policy changes to the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982, P.L. 97-248. The important technical and policy changes are as follows:

Medicare Coverage of Federal Employees

Section 309(a)(11) of the law clarifies the definition of "Medicare-qualified Federal employment" and the conditions under which dependents of transitionally insured Federal employees become entitled to Medicare. The clarification provides that

dependents of transitionally insured Federal employees are eligible for Medicare on the same basis as those dependents who qualify for Medicare on the employment record of any Social Security Title II fully insured individual. This amendment, which became effective on January 1, 1983, removed an inequity from provisions in TEFRA.

Supplementary Medical Insurance (SMI) Premium

TEFRA changes the manner in which the SMI premium is calculated, but makes it impossible to invoke the 10 percent annual penalty provision for beneficiaries who enroll late in Part B of Medicare. This problem arose due to an apparently inadvertent failure to cross-reference TEFRA to other sections of then-current law.

The Technical Corrections Act addresses this problem by clarifying that the increased SMI premium imposed for late enrollment would continue to be imposed. This technical amendment became effective as of January 1983 and has significant fiscal impact for HCFA.

Professional Standards Review Organizations (PSRO) Evaluations

TEFRA repeals the PSRO program and requires the Secretary to enter into contracts with peer review organizations for utilization and quality control if a qualified organization is available in a geographical area.

P.L. 97-448 directs the Secretary to disregard PSRO evaluations conducted during the first two quarters of FY 1982. This provision conveys Congress' intent that existing PSROs compete on an equal footing during the contract negotiations system authorized under TEFRA and that their contract proposals be considered based on a fair evaluation of efficiency and effectiveness. This provision applies to contracts entered into or renewed on or after enactment of TEFRA, i.e., September 3, 1982.

Hospice Care

Under the hospice provisions of TEFRA, a participating hospice is required to provide certain care services directly. Other hospice services may be furnished through arrangements with other parties. TEFRA also requires the Secretary to continue existing hospice demonstration projects until the effective date of the hospice benefit.

P.L. 97-448 provides that as of November 1, 1983, hospices participating in HCFA demonstrations will be exempt from meeting the requirement that certain core services be provided directly. The exemption would affect only one hospice (Genessee Region Home Care Association in Rochester, N.Y.). The demonstration project can be continued until September 30, 1986, even though it acts as a channeling agency for the provision of hospice care rather than providing services directly. If the hospice is continued after September 30, 1986, it will be subject to all other requirements imposed on other hospices.

P.L. 97-455 - The Virgin Islands Tax Reduction Act

Enactment date: January 12, 1983

The Virgin Islands Tax Reduction Act, H.R. 7093, contains amendments pertaining to continuing disability investigations, including two provisions affecting Medicare. They are as follows:

Continued Payment of Disability Benefits During Appeal

Section 2 of the law permits Disability Insurance (DI) beneficiaries to elect to continue their benefits, including Medicare, through the appeals process to the Administrative Law Judge (ALJ) decision on benefit termination cases. However, it stipulated that in the case where termination of benefits is upheld by the ALJ, the continued benefits (except Medicare benefits) are treated as overpayments and subject to the waiver requirements of present law. Prior law required Medicare benefits to be terminated the month after the month in which notice of termination of entitlement under the DI program was mailed to the beneficiary, except where a DI beneficiary works despite the continuance of his or her disability condition.

The new provisions also provides that payment of benefits may begin with February 1983 for termination decisions made by State agencies where a timely appeal is pending or filed at the time of enactment, and benefits may be elected to be continued during appeal on termination decisions made from enactment, i.e., January 12, 1983, through September 30, 1983. Benefit payments will cease no later than June 1984.

Periodic Reviews of Disability Cases

Section 3 of the law gives the Secretary discretion to reduce the flow of continuing disability investigations cases on a State-by State basis depending on State workloads and staffing requirements. The slowing of the review is allowed even if it means that the initial periodic review cannot be completed within three years. This provision was effective upon enactment.

P.L. 98-21 Title VI of the Social Security Amendments of 1983

Prospective Payment Provisions

Enactment date: April 20, 1983

Prospective Payment System

Effective with hospital cost-reporting periods beginning on or after October 1, 1983, Medicare payment for inpatient operating costs will be based on a fixed amount, determined in advance, for each case, according to one of 468 diagnosis related groups (DRGs) into which a case is classified. The prospective payment will be considered payment in full; hospitals are prohibited from charging beneficiaries more than the statutory deductible and coinsurance.

This system replaces the retrospective cost reimbursement system and the cost-per-case limits and rate of increase ceiling created by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), P.L. 97-248, for most hospitals. The new

prospective payment system will be structured to be "budget neutral" through FY 1985; that is, payments for Medicare inpatient hospital costs under the prospective payment system will be no more or less than projected under the TEFRA provisions.

Hospitals Covered

The prospective payment system will apply to all Medicare participating hospitals except psychiatric, long-term care (with an average stay greater than 25 days), children's, and rehabilitation hospitals, and hospitals outside of the 50 states and the District of Columbia. Distinct-part rehabilitation and psychiatric units of acute care hospitals are also exempt. These hospitals and hospital units will continue to be reimbursed their reasonable costs subject to the target rate of increase limits enacted in TEFRA.

Special treatment is provided for hospitals which (because of locations, weather and travel factors, or absence of other hospitals) are designated by the Secretary as sole community providers. Payment to these hospitals during the transition period and afterwards will be made at the rate specified for the first year of implementation for other hospitals; i.e., 75 percent of the payment based on the hospital's cost experience and 25 percent on the regional DRG rate. The Secretary must also make adjustments for fixed and core staff costs incurred in the event of a five percent decrease in workload from a previous year due to circumstances beyond the hospital's control.

Exceptions and adjustments may be made, as the Secretary finds appropriate, to account for the special needs of public or other hospitals serving a disproportionately large number of low-income and Medicare Part A patients, hospitals that are national or regional referral centers (including rural hospitals with over 500 beds), hospitals involved extensively in cancer research and treatment, and hospitals in Alaska and Hawaii.

Services Covered

Effective October 1, 1983, all non-physician services provided in an inpatient setting will be paid only as inpatient hospital services under Part A. The Secretary may waive this restriction during the three-year transition period for hospitals that, prior to October 1, 1982, have allowed direct billing under Part B so extensively that the immediate implementation of the restriction would threaten the stability of patient care. Part B billings made under such a waiver will be deducted from payments made to the hospitals under the prospective system. At the end of the waiver period, the Secretary may provide for Part A payment methods appropriate to the organizational structure of the institution.

Transition Period

The prospective payment system will be phased in over a three-year period by cost-reporting periods that begin on or after October 1, 1983. During this time, payment rates will be a blend of hospital-specific amounts based on each hospital's cost experience and national and regional (for nine census divisions) DRG amounts for both urban and rural hospitals.

In the first cost-reporting period under prospective payment, the Medicare payment per discharge will be:

- o 25 percent of the regional DRG rate; plus
- o 75 percent of the hospital-specific rate.

In the second cost-reporting period, the Medicare payment per discharge will be:

- o 50 percent of a combination of national and regional DRG rates (25 percent national, 75 percent regional); plus
- o 50 percent of the hospital-specific rate.

In the third and last cost-reporting period of the system's phase-in, the Medicare payment per discharge will be:

- o 75 percent of a combination of national and regional rates (50 percent national, 50 percent regional); plus
- o 25 percent of the hospital-specific rate.

Effective with hospital cost-reporting periods beginning on or after October 1, 1986, Medicare payment will be 100 percent of the national urban or rural DRG rate for each discharge.

Calculation of Hospital-Specific Costs

The portion of the Medicare payment per discharge based on hospital cost experience will be the hospital's target amount as calculated under the TEFRA rate-of-increase limits, without regard to Section 223 limits, penalties or bonuses, and with annual updates for inflation. Adjustments can be made to base year costs to make them comparable to the inpatient costs under the prospective system. For example, the base year costs for nonprofit hospitals whose employees now would be covered under Social Security (based on another provision of the law) will be increased to reflect additional costs that would have been incurred in the base year if the hospital had been in the Social Security system.

Calculation of DRG Rates

Using the most recent cost report data available, allowable inpatient operating costs per discharge will be determined for individual hospitals. The costs then will be updated for fiscal year 1983 by the estimated national average rate of inflation in hospital costs. For fiscal year 1984, the hospital per discharge costs will be updated by the projected national hospital marketbasket rate of inflation plus one percent. The per discharge costs then will be standardized by excluding estimated indirect medical education costs and by adjusting for variations in case-mix and area wages. Urban (by Metropolitan Statistical Area) and rural averages then will be computed for the United States and the nine census divisions. The standardized average amounts will be reduced to offset additional payments for unusually long-stay or expensive cases (i.e., outliers) and to achieve budget neutrality, if necessary, with projected reimbursement under the TEFRA limitations. The standardized amounts

also will be adjusted by the estimated cost of inpatient services billed under Part B in the base year that now will be payable under the prospective rate. The DRG-specific rates for urban and rural areas in the United States and the regions then will be calculated by applying a weighting factor reflecting the relative hospital resources used for discharges within the various DRGs. Finally, the DRG-specific rates will be adjusted to reflect differences in area hospital wages compared to the national average wage level.

Annual Increases

For fiscal year 1985, the standardized amounts will be increased by the projected rate of increase in the hospital marketbasket plus one percent. These standardized amounts could be reduced for outlier payments and to achieve budget neutrality.

Beginning with fiscal year 1986, the annual increase in DRG rates will be determined by the Secretary. The increases must take into account amounts necessary for the "efficient and effective delivery of medically appropriate and necessary care of high quality." The Prospective Payment Assessment Commission will review evidence concerning factors that may affect the level of the annual increase and provide its recommendations to the Secretary no later than April 1 of each year. The Secretary will publish the proposed annual increase factor in the Federal Register by June 1 and the final annual increase factor by September 1 of each year.

DRG Recalibration

The Secretary must adjust the DRG classifications and weighting factors for fiscal year 1986 and at least every four years thereafter to reflect changes in treatment patterns, technology, and other factors affecting hospital resource utilization.

The Prospective Payment Assessment Commission will consult with the Secretary and make recommendations on the need for adjustments based on its evaluation of new practices, technologies, and treatment modalities. The Commission will also report to Congress on its evaluation of adjustments made by the Secretary.

Atypical Cases ("Outliers")

Payments in addition to the DRG rate will be made for cases which exceed the mean length of stay for the DRG by a fixed number of days, or by a certain number of standard deviations (whichever is the fewer number of days). At a hospital's request, the Secretary may make additional payments for cases whose costs exceed a fixed multiple of the appropriate DRG rate or other fixed amount. The additional payment will approximate the marginal costs of care beyond the outlier cut-off criteria (days or dollar amounts).

The total proportion of outlier payments cannot be less than five percent nor more than six percent of total DRG-related payments in any year.

Capital Expenses

General

Capital-related expenses are specifically excluded from the prospective payment system until October 1, 1986. Until that time, they will be reimbursed on a reasonable cost basis. The Secretary must report to Congress, within 18 months, on a method to incorporate capital-related costs (including return on equity) into the prospective payment system.

The law specifies that when capital-related costs are brought into the prospective system there is no assurance that capital expenditures obligated on or after implementation of that system will be treated in the same manner as expenditures obligated before the implementation date.

Return on Equity

Effective for cost-reporting periods beginning on or after the date of enactment, the rate of return on equity for inpatient hospital services in proprietary hospitals will be reduced from one-and one-half times to the average rate of interest paid during the cost-reporting period by the Federal Treasury on the assets of the Hospital Insurance Trust Fund.

Section 1122 Review

If legislation is not enacted before October 1, 1986 to deal with capital, Medicare payment will be made for capital projects obligated after September 30, 1986 only if the expenditures have been approved under Section 1122. States will be required to enter into agreements with the Secretary to establish Section 1122 if their agencies have not already done so.

Capital expenditures made by health care facilities will be exempt from Section 1122 review if 75 percent of their patients who are expected to use the service are health maintenance organization (HMO) or competitive medical plan (CMP) enrollees; if the services and facilities are needed for an HMO or CMP to operate efficiently and economically; and if the services are not otherwise readily accessible to an HMO or CMP due to at least one of the following reasons:

- o the facilities do not provide common services at the same site;
- o the facilities are not available under a contract of reasonable duration;
- o full and equal medical staff privileges are not available;
- o the arrangements are not administratively feasible; or
- o the services are more costly than if provided directly by the HMO or CMP.

In addition, effective upon enactment, the financing of Section 1122 reviews will be made from general revenues. Hospitals will be required to make their capital budgets available to the Section 1122 or other appropriate agency. States may set their own dollar thresholds for review, not to exceed a maximum of \$600,000.

Medical Education Expenses

Direct Costs

The direct costs of approved educational programs are specifically excluded from the prospective payment and will be paid on the basis of reasonable cost.

Indirect Costs

The indirect costs of medical education are not included in the prospective payment and will be paid at twice the factor used to adjust for such costs, by applying the same methodology currently in effect.

Cost Reporting

A system of cost reporting for hospitals under the prospective payment system will be maintained during the three-year transition period and for at least two years afterward (until the end of fiscal year 1988).

Administrative and Judicial Review

Administrative and judicial review is permitted except for the DRG classification and weights and the level of the payment necessary to maintain budget neutrality in fiscal years 1984 and 1985.

Group appeals must now be made in the judicial district in which the greatest number of such providers is located. Appeals to the Provider Reimbursement Review Board for action for judicial review brought by providers under common ownership or control will have to be brought as a group when the matter involves a common issue.

State Cost Control Systems

The Secretary has the authority to approve Medicare payment under a State cost control system if the system meets the four requirements enacted in TEFRA plus two additional requirements. To qualify, State systems must:

- o apply to substantially all acute care hospitals in the State;
- o apply to at least 75 percent of all inpatient revenues or expenses;
- o provide assurances that payors, hospital employees, and patients are treated equitably;

- o provide assurances that the State's system will not result in greater Medicare expenditures over a three-year period;
- o not preclude HMOs or CMPs from negotiating directly with hospitals concerning payment for inpatient services; and
- o prohibit payments under Part B for nonphysician services provided to inpatients, unless waived in accordance with regulations which the Secretary is required to publish.

The Secretary can neither deny a State's application because it is not based on a DRG payment methodology, nor require that Medicare expenditures under the state system be less than would have been made under the Federal prospective payment system.

The Secretary shall approve State applications which meet the preceding requirements plus additional requirements that the system must:

- o be operated directly by the State or entity designated by state law;
- o use prospective methodology;
- o provide for hospital reports, as required by the Secretary;
- o provide satisfactory assurances that it will not result in admission practices which will reduce treatment to low income, high cost, or emergency patients;
- o not reduce payments without 60 days notice to the Secretary and to hospitals; and
- o provide satisfactory assurances that, in developing the program, the State has consulted with local officials concerning the impact on public hospitals.

The Secretary must respond to States applying under these conditions within 60 days following submission of the request.

Existing State Programs

States now operating approved cost control systems (Maryland, New Jersey, New York, and Massachusetts) will be allowed to continue as long as they meet the requirements for which the Secretary has authority to grant approval.

The Secretary must modify the demonstration agreements with the States of New York and Massachusetts, if requested by the State or another party to the agreement, so that the demonstrations are not required to keep the State rate of increase in Medicare hospital expenditures one-and one-half percentage points below the national rate of increase.

The Secretary must judge the effectiveness of the existing State systems during the three cost-reporting periods beginning on or after October 1, 1983. For the purpose of the evaluation, those States have the option of having either the rate of inflation in aggregate payments or payments per admission or discharge compared to the national rate of increase.

Reduction in Payments

If the cost of a State system exceeds the amounts that would have been paid under the Federal system over a three-year period, the Secretary may reduce subsequent payments to hospitals by the amount in excess.

Admissions and Quality Review - Contracts with Utilization and Quality Control Peer Review Organizations (PROs)

Requirements for PRO Agreements

Effective October 1, 1983, hospitals under a prospective payment system (Federal or State) would have to contract for review services with a PRO, if one exists in their areas. Beginning November 15, 1984, hospitals must have a contract with a PRO as a condition for Medicare payment. If there is no PRO in the area, the hospital will not receive payment. Hospitals which have contracted with a PRO that is subsequently terminated by the Secretary will not be penalized for 6 months while the Secretary contracts with a new PRO.

In the absence of a qualified physician-sponsored or physician-access organization, intermediaries may qualify as PROs. However, intermediaries may not become PROs prior to November 15, 1984.

PRO Review Functions

The specified functions of a PRO include reviewing:

- o the validity of diagnostic information provided by hospitals;
- o invasive diagnostic and therapeutic procedures (e.g. pacemaker insertions);
- o the completeness, adequacy, and quality of care provided;
- o the appropriateness of admissions and discharges; and
- o the appropriateness of care for which outlier payments are made.

In addition, PROs must achieve admissions and quality objectives as follows:

Admission Objectives

- I Reduce admissions for procedures that can safely be performed in an ambulatory surgical setting or on an outpatient basis.
- II Reduce inappropriate or unnecessary admissions or invasive procedures.

Quality Objectives

- I Reduce unnecessary admissions due to substandard care in a previous admission.
- II Assure the provision of medical services that when not performed have "significant potential" for causing serious patient complications.

III Reduce inappropriate or unnecessary admissions by specific practitioners or specific hospitals.

III Reduce the risk of mortality associated with selected procedures and/or conditions requiring hospitalization.

IV Reduce unnecessary surgery or other invasive procedures.

V Reduce avoidable postoperative complications.

Payments to PROs

PRO review is considered a Part A hospital cost but the PRO will be paid directly by the Secretary under a fixed price contract for a term of 2 years. The Secretary will determine the PRO budget amount, which can be no less than the fiscal year 1982 review rate for both direct and administrative costs, adjusted for inflation. PRO funding will come from the Hospital Insurance Trust Fund and will not be subject to appropriations.

Penalties

Based on PRO findings and procedures, the Secretary may deny payment for unnecessary or inappropriate admissions, and/or require hospitals to take necessary action to correct unacceptable medical or other practices.

Studies, Demonstrations and Reports

The Secretary is required to study and report to Congress on the following:

- o Capital-Related Costs - the method by which capital-related costs such as return on equity, associated with inpatient hospital services can be included in the prospective payment system. Due date: October 1984.
- o Annual Impact Report - the impact in the previous year of the prospective payment methodology on providers, beneficiaries, and other payors of hospital care, and the impact of computing DRG rates by census division, rather than on a national basis. The report must include recommendations for appropriate legislative changes. Due date: by the end of each year for 1984 through 1987.
- o Skilled Nursing Facilities
 - the impact of hospital prospective payment systems on SNFs and recommendations concerning SNFs. Due date: by December 31, 1983.
 - conduct demonstrations with hospitals in areas with critical shortages of SNFs to study the feasibility of providing alternative systems of care or methods of payment.
 - the effect of a single limit of SNF reimbursement on hospital-based SNFs, given the differences (if any) in the patient populations served by such facilities and by community-based SNFs. Due date: by December 31, 1983.

- o Inpatient Physicians' Services - During fiscal year 1984, begin the collection of data necessary to compute, by DRGs, the amount of physician charges for services furnished to hospital inpatients classified in those DRGs. The report to Congress must include recommendations on the advisability and feasibility of determining payments for inpatient physicians' services on a DRG-type classification. Due date: June 1, 1985.
- o Urban/Rural Rates - the feasibility and impact of eliminating or phasing out separate urban and rural DRG rates. Due date: December 31, 1985 as part of the 1985 annual impact report.
- o Prospective Payment for Exempted Hospitals - the feasibility and methodology by which hospitals not included in the prospective payment system can be paid on a prospective basis for inpatient services. Due date: at the end of 1985 as part of the 1985 annual report.
- o Payments for Outliers and Modifications to the DRGs - the appropriateness of factors used to compensate hospitals for outlier cases and the feasibility and advisability of modifying the DRGs by the application of severity of illness, intensity of care or other factors. Due date: at the end of 1985 as part of the 1985 annual report.
- o All Payer System - the feasibility and desirability of all inpatient hospital payers participating in a prospective payment system, including consideration of cost-shifting to nonfederal payers and the impact on health insurance costs and premiums paid by employers and employees. Due date: at the end of 1985 as part of the 1985 annual report.
- o Impact on Admissions - the feasibility of making a volume adjustment in the DRG rates or requiring preadmission certification in order to minimize the incentive to increase admissions. Due date: at the end of 1985 as part of the 1985 annual report.
- o Impact of State Systems - the overall impact of state hospital payment systems approved under the Social Security Act on the Medicare and Medicaid programs, on payments and premiums under private health insurance plans, and on tax expenditures. Due date: at the end of 1986 as part of the 1986 annual report.
- o Sole Community Providers - study and make legislative recommendations on an equitable method of reimbursing sole community providers, taking into account their unique vulnerability to substantial variations in occupancy. Due date: by April 1, 1985.
- o Information Transfer Between Parts A and B - examine ways to coordinate an information transfer between Parts A and B of Medicare, particularly where a denial of coverage is made under Part A but no adjustment is made in the reimbursement to admitting physician(s). Due date: by April 1, 1985.

- o Uncompensated Care Costs - the appropriate treatment of uncompensated care costs and adjustments that might be appropriate for large teaching hospitals in rural areas. Due date: by April 1, 1985.
- o Making Hospital Cost Information Available - the advisability of hospitals making information available on the cost of care to patients financed by public and private payers. Due date: by April 1, 1985.
- o The Territories, Puerto Rico, and the Virgin Islands - a methodology for including hospitals located outside of the fifty States and the District of Columbia under a prospective payment system. Due date: by April 1, 1984.

Prospective Payment Assessment Commission

Membership

The Director of the Congressional Office of Technology Assessment (OTA) will provide for appointment of a 15 member commission of independent experts by April 1, 1984 for a term of 3 years. Initial terms may be shorter so that the terms of no more than seven members expire in any year. The membership must provide expertise and experience in the provision and financing of health care and must include, at least, physicians, registered nurses, employers, third-party payers, individuals with expertise in the conduct and interpretation of biomedical, health services, and health economics research, and individuals with expertise in the research and development of technologic and scientific advances in health care.

Nominations for commission members will be sought from national organizations representing physicians (including medical specialty organizations), registered nurses, skilled health professionals, hospitals (including teaching hospitals), manufacturers of health care products, the business community, health benefit programs, employers, and the elderly.

Authority

Subject to the review of OTA, the Commission may:

- o employ and fix compensation for up to 25 persons, as necessary to carry out its functions;
- o seek necessary assistance and support from appropriate Federal agencies, including access to relevant information to assure coordination of activities;
- o award grants or contracts, including those for original research and experimentation, including clinical research. Clinical services provided as part of a research project must have the Secretary's concurrence for reimbursement. The authority to conduct clinical research is also extended to the Secretary as it relates to the Commission's duties and functions;

- o make advance or other payments related to its work;
- o provide transportation and subsistence to unpaid volunteers; and
- o prescribe necessary rules and regulations for its internal organization and operation.

Duties and Functions

- o Review and provide recommendations to the Secretary on DRG recalibrations for FY 1986 and at least every four years thereafter;
- o Review and provide recommendations to the Secretary on the annual increase factor beginning with FY 1986; and
- o In order to make recommendations on DRG recalibrations, collect and assess information on the safety, efficacy and cost-effectiveness of new and existing medical and surgical procedures and services, including regional variation in medical practice, lengths of hospitalization and other patient-care data, with special attention to treatment patterns for costly or inappropriate care not conducive to increasing quality.

Support and Oversight

Necessary appropriations will be made from the Medicare Trust Funds (85 percent from the Hospital Insurance Trust Fund and 15 percent from the Supplementary Medical Insurance Trust Fund) to fund the Commission's activities.

The OTA has unrestricted and immediate access to all deliberations, records and data of the Commission and must report annually to Congress on the functions and progress of the Commission and on the status of the assessment of medical procedures and services.

Other Title VI Provisions

Delay of Single Reimbursement Limit for Skilled Nursing Facilities

The effective date for the single reimbursement limit for hospital-based and community-based SNFs is delayed to cost reporting periods beginning on or after October 1, 1983.

Shift in Medicare Premiums to Coincide with Cost-of Living Increase

The Part A and Part B premiums will remain at the June 1983 amounts through December 1983, after which premium adjustments will be made on a calendar year basis. The Part B premium will be set at one-half the actuarial rate from January 1984 through December 1985.

The Secretary will develop and promulgate new premiums during the month of September prior to the calendar year in which the premiums will be effective. The actuarial assumptions and other bases for arriving at adequate premium amounts will be issued at the same time.

On Lok Demonstration

Within 30 days following enactment the Secretary must approve, with Appropriate terms and conditions, the applications of the On Lok Senior Health Services (dated July 2, 1982) and the California Department of Health Services (dated November 1, 1982) for a 36-month waiver of certain Medicare and Medicaid requirements to carry out a demonstration project for capitated reimbursement of comprehensive long-term care services.

P.L. 98-90 - To Increase the Cap Amount Allowable for Medicare Reimbursement of Hospices Enactment date: August 29, 1983

As enacted, H.R. 3677 increases the cap amount allowable for reimbursement of hospices under the Medicare program. Under the legislation the original statutory formula for calculating the cap amount is deleted and a fixed amount of \$6500 per Medicare hospice patient is substituted. The cap amount will be increased annually for inflation by the medical care component of the consumer price index. The cap will continue to be applied to aggregate Medicare payments to a hospice.

Legislation Enacted During FY 1983 Affecting Medicare Eligibility

1. P.L. 97-448, 1/12/83, Technical Corrections Act of 1982, provides that dependents of Federal employees insured for hospital insurance under Medicare based on remuneration for services prior to 1/1/83, may be entitled to hospital insurance benefits without the need for the employee to be entitled also. This amendment thus removed an inequity from the TEFRA provision on Medicare for Federal employees which had imposed a requirement for entitlement on the dependents of the Federally insured which did not apply to dependents of non-Federal workers.
2. P.L. 97-455, 1/12/83, Taxes on Virgin Island Source Income; Disability Benefits, Section 2 provides that payment of terminated disability benefits and Medicare will be continued, at the individual's election, during the period when an appeal of the termination is pending.
3. P.L. 98-21, 4/20/83, Social Security Amendments of 1983:

Section 309 permits hospital insurance entitlement for disabled men entitled to father's benefits on the same basis as such coverage is available to disabled women entitled to mother's benefits.

Section 332 relaxes the rules for establishing insured status for individuals who had previously been entitled to a period of disability prior to attainment of age 31. The provision was effective for both monthly benefit and Medicare for the disabled purposes beginning with 5/83.

Section 606 provides for a shift in the announcement date and effective date of the Medicare premium changes. The Secretary will promulgate each September the premiums that will be applicable to Part A and Part B of Medicare beginning with the following January.

PART II

**ANNUAL REPORT
ON THE**

**END-STAGE RENAL DISEASE PROGRAM
(CALENDAR YEAR 1983)**

PART II END STAGE RENAL DISEASE

The End-Stage Renal Disease (ESRD) part of the report is prepared in accordance with Section 1881(g) of the Social Security Act, and addresses the 15 specific requests for data enumerated therein. It covers activities related to the care of ESRD patients that took place in calendar year 1983, and includes information on the number of patients utilizing the various forms of treatment, the costs involved, discussions of cost savings experiments, and basic kidney research conducted during the year.

The total dialysis population increased by 9.5 percent in 1983 to 71,987 from 65,765 in 1982. The home dialysis population increased by 16.3 percent, to 13,645 from 11,733 in 1982. The net increase in home patients was due largely to the growth of continuous ambulatory peritoneal dialysis (CAPD) from 6,523 patients in 1982 to 8,532 patients in 1983. CAPD now accounts for 62.5 percent of all home patients. At the end of 1983, the home dialysis population accounted for 18.9 percent of the total dialysis population, a net increase of 1.1 percent over 1982.

The number of transplants performed increased by 14.0 percent in 1983, to 6,112 from 5,358 in 1982. Patients transplanted in 1983 accounted for 8.5 percent of the total ESRD population, a net decrease of 1.5 percent over 1982. The percentage of total transplants performed with kidneys from living related donors increased 6.3 percent from 1982 figures, while cadaveric transplants increased 17.6 percent.

Total expenditures for services rendered during calendar year 1983 were more than \$1.8 billion, based on bills posted as of December 31, 1984. The 1983 figure will increase as bills continue to be posted. The average payment rate for both hospital and freestanding dialysis units for dialysis was \$160 per treatment prior to August 1, 1983 when Section 2145 of P.L. 97-35 was implemented. Thereafter, the average payment rates per treatment were \$130.41 in hospital-based facilities and \$125.59 in independent facilities. This dual rate prospective payment system excludes physicians' fees. A monthly capitation payment system (MCP) has been used to pay physicians for their ESRD related professional services. The MCP was effective August 1, 1983 and replaced the initial method. The average kidney acquisition charge in 1983 was \$10,065 for a living related donor kidney and \$9,850 for a cadaveric kidney. The average estimated kidney acquisition costs were \$8,452 and \$8,298, respectively. The average estimated cost for a transplant in 1983 was \$27,144, excluding physicians' services.

CHAPTER I

GENERAL

A. SCOPE OF REPORT

This report will address the items specified in Section 1881(g) of the Social Security Act, which requires the following information:

1. The number of patients, nationally and by renal disease Network, on dialysis (self-dialysis or otherwise) at home and in facilities.
2. The number of new patients entering dialysis at home and in facilities during the year.
3. The number of facilities providing dialysis and the utilization rates of those facilities.
4. The number of kidney transplants, by source of donor organ.
5. The number of patients awaiting organs for transplant.
6. The number of transplant failures.
7. The range of costs of kidney acquisitions, by type of facility and by region.
8. The number of facilities providing transplants and the number of transplants performed per facility.
9. Patient mortality and morbidity rates.
10. The average annual cost of hospitalization for ancillary problems in dialysis and transplant patients, and drug costs for transplant patients.
11. Medicare payment rates for dialysis, transplant procedures, and physician services, along with any changes in such rates during the year and the reasons for changes.
12. The results of cost-saving experiments.
13. The results of basic kidney disease research conducted by the Federal Government, private institutions, and foreign governments.
14. Information on the activities of Medical Review Boards and other Network organizations.
15. Estimated program costs over the next five years.

B. END-STAGE RENAL DISEASE PROGRAM HIGHLIGHTS DECEMBER 31, 1983

REIMBURSEMENT¹

The following table shows reimbursement made by the Medicare program for services provided to ESRD patients in 1983:

<u>Type of Payment</u>	<u>Amount of Payment (Millions)*</u>
Inpatient	\$ 601.8
Outpatient	846.7
Physician/Supplier	396.8
Home Health/Skilled Nursing Facility	9.5
Total	<u>\$1854.8</u>

*Not Final Figures - Bills posted through December 31, 1984

DIALYSIS TREATMENT MODALITIES²

<u>Dialysis Type and Setting</u>	<u>Number of Patients as of:</u>	
	<u>12/31/82</u>	<u>12/31/83</u>
In-Unit Staff-assisted Hemodialysis	51,499	55,554
In-Unit Staff-assisted Peritoneal Dialysis	874	742
In-Unit Self-hemodialysis	1,060	1,475
In-Unit Self-peritoneal Dialysis	11	3
Home Hemodialysis	4,394	4,323
Home Peritoneal Dialysis	816	790
Continuous Ambulatory Peritoneal Dialysis	6,523	8,532
Self-dialysis Training: Hemodialysis	408	379
Peritoneal	19	33
CAPD	161	156
Total Dialysis Patients	<u>65,765</u>	<u>71,987</u>

RENAL TRANSPLANTS²

The following table shows the number of transplants performed for calendar years 1982 and 1983, by type of donor:

<u>Type of Donor</u>	<u>1982</u>	<u>1983</u>
Living	1,677	1,784
Cadaveric	3,681	4,328
Total	<u>5,358</u>	<u>6,112</u>

TRANSPLANT CHARGES³

Average kidney acquisition charges for 1983 were:

Living related donor kidney	\$10,065
Cadaveric donor kidney	\$ 9,850

RENAL FACILITIES⁴

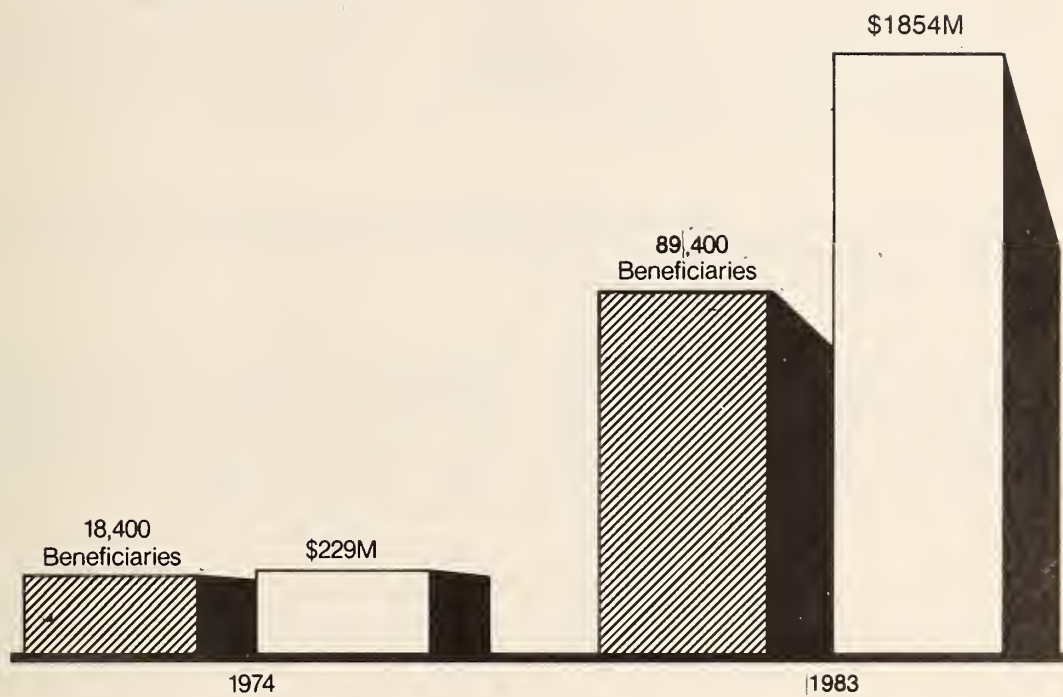
These figures represent all Medicare facilities approved to provide maintenance dialysis services to ESRD patients as of December 31, 1983:

<u>Total</u>	<u>Profit</u>			<u>Non-Profit</u>			
	<u>Hospitals</u>	<u>Free-Standing Facilities</u>	<u>Hospital Satellites</u>	<u>Hospitals</u>	<u>Free-Standing Facilities</u>	<u>Hospital Satellites</u>	<u>Unknown</u>
1246	14	488	0	571	131	30	12

1. Source: Weekly Health Insurance Merge (WHIM) Record (HCFA).
2. Source: ESRD Facility Survey Tables (BDMS, HCFA).
3. Source: Bureau of Eligibility, Reimbursement and Coverage (HCFA).
4. Source: National Listing of Providers Furnishing Kidney Dialysis and Transplant Services (BDMS, HCFA).

Figure 1

ESRD Program Growth



D. DATA COLLECTION

All information concerning the numbers of patients in the various treatment modalities, and the number of transplants performed, was gathered through use of a data collection form known as the End-Stage Renal Disease Facility Survey. For 1983, the Facility Survey was distributed twice, the first time to cover the first six months of calendar year 1983, and the second time to cover the last six months of the year.

A total of 1,255 facilities which perform some form of maintenance dialysis and 160 hospitals which perform kidney transplants were requested to complete a Facility Survey (see Table 1). The rate of compliance with that request was 100 percent.

The number of facilities surveyed does not equal the total number of ESRD certified facilities in the country. Some ESRD hospitals were excluded from consideration because they provide only backup dialysis on an acute basis, rather than routine outpatient maintenance dialysis. Other facilities were not requested to complete a Facility Survey because they were so recently certified that there was not sufficient time to include them in the survey population.

The data reported via the Facility Survey delineates totals for all patients with end-stage renal disease. That is, the data are not differentiated between patients who have attained entitlement to Medicare benefits and those who have not, within the various treatment modalities.

Although we have no data to definitely indicate what portion of the patients in any particular treatment modality were recipients of Medicare benefits, we know through the Facility Survey that at the end of 1983, 88.4 percent of all patients were entitled to Medicare benefits, 5.4 percent had applications for Medicare entitlement pending, and 6.2 percent were not Medicare eligible.

CHAPTER II

FACILITIES

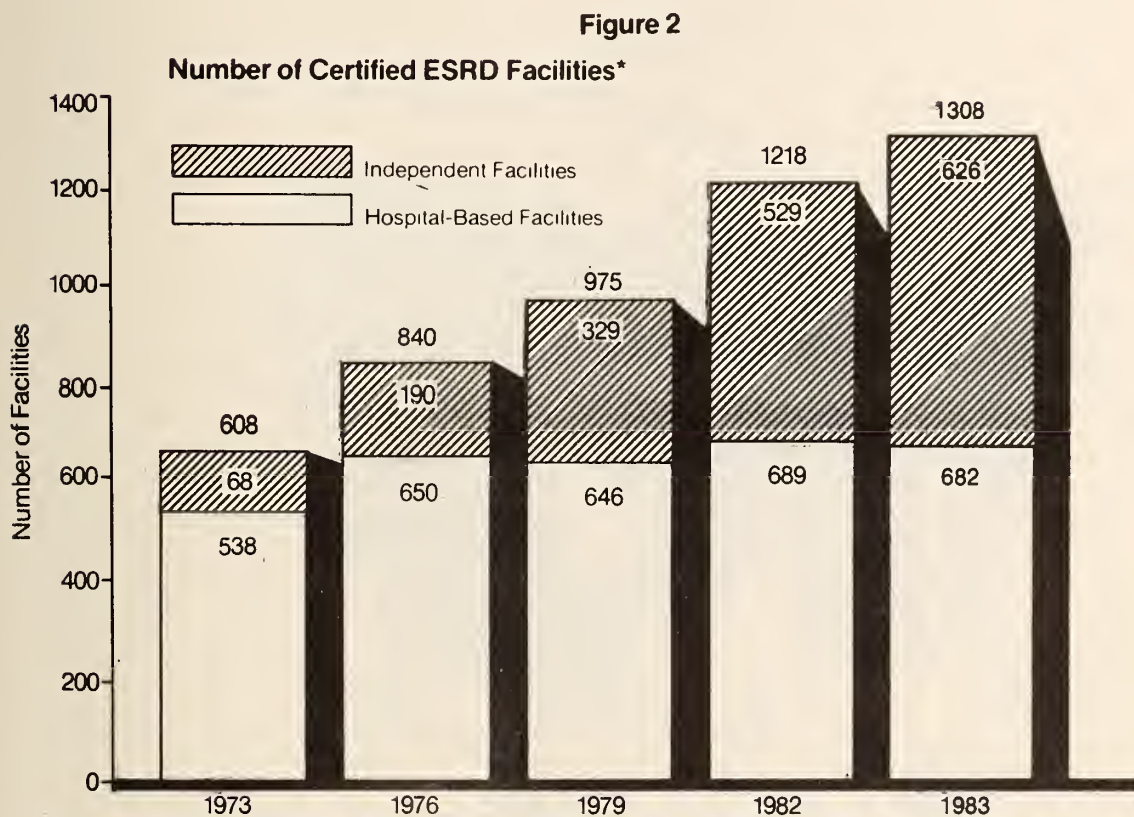
TABLE 1

A. ESRD FACILITIES SURVEYED AND REPORTING BY STATE

STATE	DIALYSIS FACILITY SURVEYED AND REPORTING	TRANSPLANT FACILITY SURVEYED AND REPORTING	STATE	DIALYSIS FACILITY SURVEYED AND REPORTING	TRANSPLANT FACILITY SURVEYED AND REPORTING
Alabama	23	2	New Mexico	12	1
Alaska	1	0	New York	89	13
Arizona	20	3	North Carolina	21	5
Arkansas	17	2	North Dakota	4	0
California	142	13	Ohio	40	9
Colorado	12	1	Oklahoma	21	4
Connecticut	16	2	Oregon	9	1
Delaware	3	0	Pennsylvania	78	8
Washington, D.C.	13	5	Puerto Rico	15	2
Florida	79	4	Rhode Island	4	0
Georgia	40	4	South Carolina	21	1
Hawaii	7	1	South Dakota	6	0
Idaho	2	0	Tennessee	25	2
Illinois	65	7	Texas	76	7
Indiana	13	2	Utah	17	3
Iowa	10	2	Vermont	1	1
Kansas	6	2	Virgin Islands	2	1
Kentucky	16	2	Virginia	43	4
Louisiana	41	5	Washington	13	4
Maine	4	1	West Virginia	9	0
Maryland	25	3	Wisconsin	21	2
Massachusetts	23	7	Wyoming	1	0
Michigan	37	10	American Samoa	1	0
Minnesota	14	3	Guam	1	0
Mississippi	22	1	Mariana Islands	1	0
Missouri	28	6			
Montana	4	0			
Nebraska	8	1	TOTALS	1,255	160
Nevada	3	0			
New Hampshire	4	0			
New Jersey	26	3			

Source: ESRD MEDICAL INFORMATION SYSTEM 1983 FACILITY SURVEYS

B. NUMBER OF CERTIFIED ESRD FACILITIES SINCE 1973



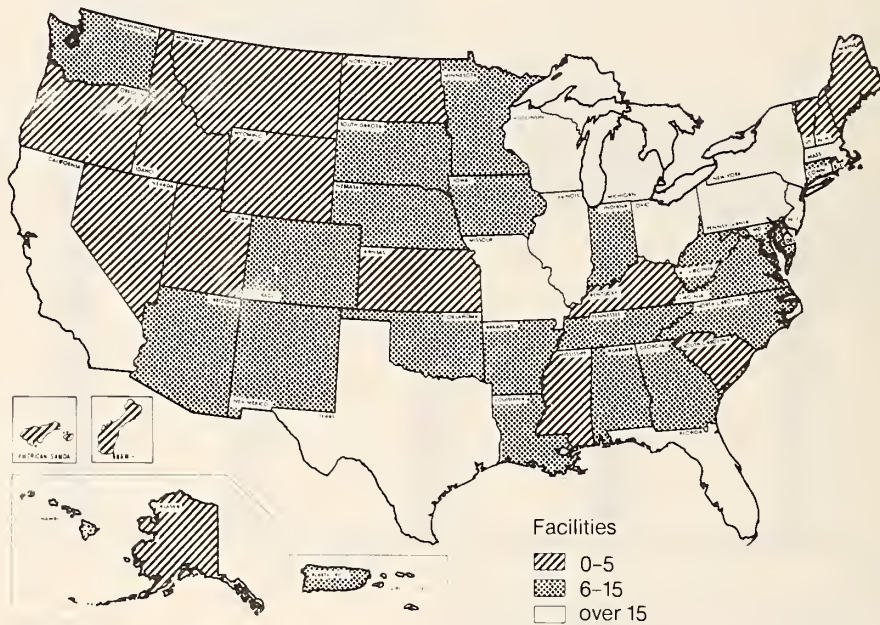
SOURCE: The National Listing of Providers Furnishing Kidney Dialysis and Transplant Services. January 1984—HCFA

*This includes all ESRD Medicare approved facilities, not just those providing outpatient maintenance dialysis.

C. DIALYSIS FACILITIES, HOSPITAL - 1983

Figure 3

Dialysis Facilities, Hospital—1983

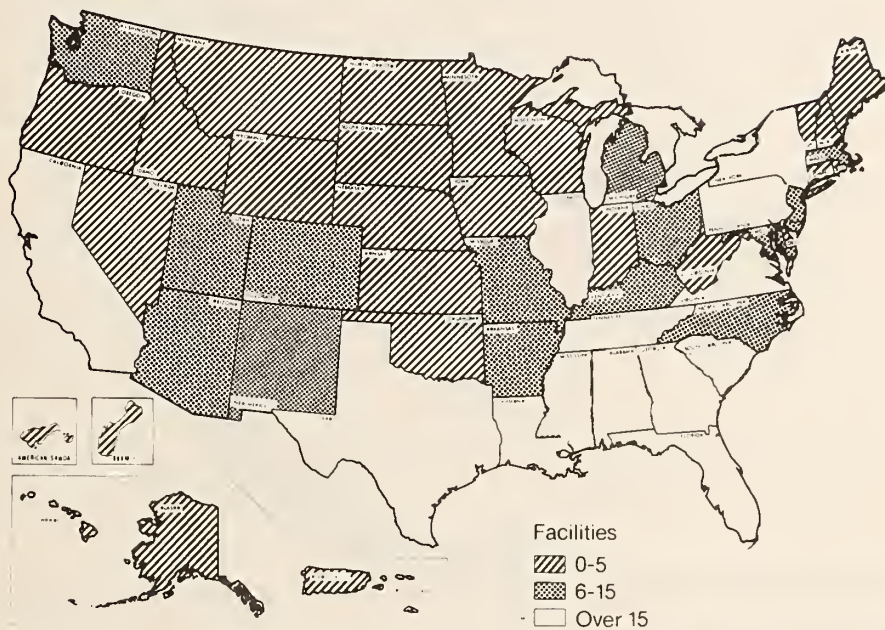


SOURCE: The National Listing of Providers Furnishing Kidney Dialysis and Transplant Services. January 1984—HCFA

D. DIALYSIS FACILITIES, INDEPENDENT - 1983

Figure 4.

Dialysis Facilities, Independent—1983

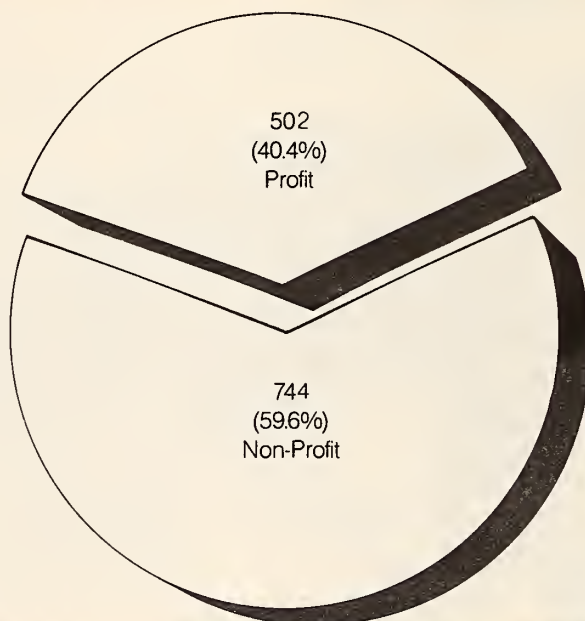


Source: The National Listing of Providers Furnishing Kidney Dialysis and Transplant Services. January 1984—HCFA

E. TYPE OF OWNERSHIP - PROFIT VS. NON-PROFIT - 1983

Figure 5

Type of Ownership—Profit vs. Non-Profit, 1246 ESRD Dialysis Providers, 1983



SOURCE: The National Listing of Providers Furnishing Kidney Dialysis and Transplant Services. January 1984—HCFA

F. MINIMUM UTILIZATION RATE STATUS OF FACILITIES

As of December 1983, there were 1,308 hospitals and facilities approved to furnish dialysis and transplantation services. Of these, 682 were hospital-based and 626 non-hospital-based. Of the hospital-based facilities, 13 provided transplantation services only, 146 provided both dialysis and transplantation, and 523 provided only dialysis services.

Dialysis

The number of certified facilities increased in 1983 by more than 7 percent (90). Compared to 1982, there was a decrease of 7 hospital-based facilities and an increase of 97 non-hospital-based. The number of approved dialysis stations has increased by approximately 7.4 percent (1,068).

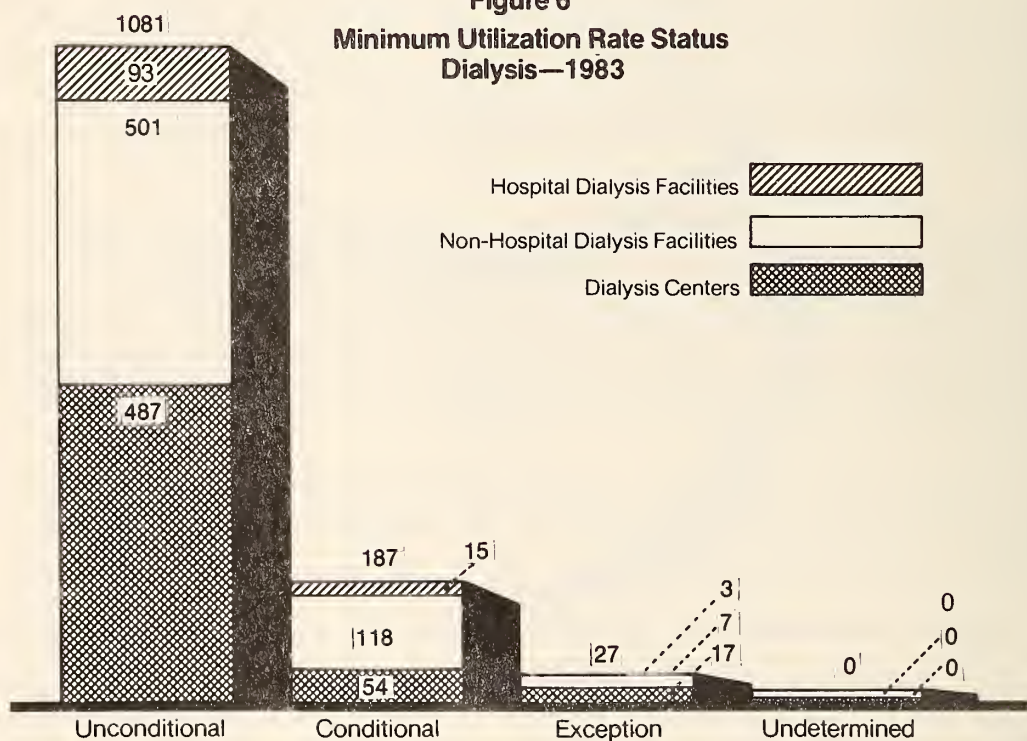
Each approved dialysis facility is certified to provide any of a variety of specialized services. These services include staff-assisted dialysis, home or self-dialysis training, and CAPD training. Over 63 percent (825) of the approved facilities are certified to provide some type of home self-dialysis training and approximately 17 percent (225) are approved to provide in-center self-care dialysis.

As a condition of coverage, all approved ESRD facilities are required to meet minimum utilization rates (MURs). Regulations specify the MURs for which a facility will receive either an unconditional or conditional certification. However, regulations permit an exception to the MUR requirements for a facility that is determined not to have sufficient patients in its service area to meet such a rate, if the facility's absence would adversely affect the achievement of ESRD program objectives.

A total of 1,308 certified facilities have been classified by MUR. Figure 6 shows a total of 1,295 dialysis facilities which have been classified according to the MUR criteria established in regulations.

G. MINIMUM UTILIZATION RATE STATUS DIALYSIS - 1983

Figure 6
Minimum Utilization Rate Status
Dialysis—1983



SOURCE: The National Listing of Providers Furnishing Kidney Dialysis and Transplant Services, January 1984—HCFA

H. TRANSPLANT

As of December 1983, there were 160 hospitals approved by the ESRD program as transplant centers.

Transplant centers are grouped according to the minimum utilization rate (MUR) certification standards in Table 2 below. To achieve unconditional certification, a hospital must perform 15 or more transplants per year; for conditional certification, a hospital must perform 7-14 transplants per year. Exception status for transplantation is granted to a hospital that furnishes renal transplantation services primarily to pediatric patients, and is approved as a renal dialysis center under CFR 42 Subpart U, but does not meet conditional or unconditional utilization standards. Most hospitals specializing in renal transplantation services for pediatric patients have been able to qualify without an exception; a few have not. The absence of an exception to provide for those few could thwart one of the objectives of the ESRD program to encourage proper distribution and effective utilization of ESRD treatment resources, while maintaining the quality of care.

TABLE 2.

MINIMUM UTILIZATION RATE STATUS - TRANSPLANT

	<u>Total</u>	<u>Unconditional</u>	<u>Conditional</u>	<u>Exception</u>	<u>Undetermined</u>
Transplant	160	118	38	4	0

I. MINIMAL UTILIZATION RATE STUDY

Under a HCFA contract, a study was conducted by Moshman Associates to investigate the relationship between utilization rates of end-stage renal disease (ESRD) centers and facilities and quality of care.

The analysis was based on a comprehensive review of patients who received care from a sample of 50 dialysis centers and facilities and 50 transplant centers. Patient information was derived from data stored in the ESRD Program Management and Medical Information System and Medicare beneficiary billing information and verified by a series of site visits.

The contractor found no statistically significant relationship between the utilization rate, charges, or quality of care at transplantation centers and dialysis facilities and centers, to indicate that larger institutions were more efficient or provided better medical care.

Economic efficiency was found to be correlated with the utilization rate for dialysis centers and facilities, but the small samples and low levels of the correlations precluded any statistical significance.

CHAPTER III

DIALYSIS

A. DIALYSIS PATIENT PROFILE

See Table 10 and Figures 7, 8, 9, 10 and 11

TOTAL

The total number of ESRD patients receiving dialysis continues to grow. As of December 31, 1983, the total dialysis population was 71,987.

INCENTER

The number of patients receiving their treatment in facilities was 58,342. This represents 81.0 percent of the total dialysis population. Of the incenter population, 96.5 percent were receiving staff-assisted outpatient maintenance dialysis; 1,478, or 2.5 percent, were performing incenter self-dialysis; and 568, or 1.0 percent, were undergoing self-care dialysis training.

HOME

The proportion of patients being treated at home is slowly increasing. There were 13,645 patients dialyzing at home at the end of 1983. This represents 19.0 percent of the total dialysis population. Of the home dialysis population, 4,323 or 31.7 percent, were using hemodialysis; 790 or 5.8 percent, were using peritoneal dialysis; and 8,532, or 62.5 percent, were using continuous ambulatory peritoneal dialysis (CAPD).

SELF CARE

Overall, patients performing some form of self-care comprise 21.7 percent of the total dialysis population. The distribution of patients in self-care over the last five years is as follows:

TABLE 3.

ANNUAL DISTRIBUTION OF SELF-CARE DIALYSIS PATIENTS

<u>Treatment Setting</u>	<u>1979</u>	<u>1980</u>	<u>1981</u>	<u>1982</u>	<u>1983</u>
Home	5,968	7,661	9,474	11,733	13,645
Incenter	620	781	1,038	1,071	1,478
Training	<u>519</u>	<u>521</u>	<u>495</u>	<u>588</u>	<u>568</u>
Total:	7,107	8,963	11,007	13,392	15,691
Percent of Total Dialysis Population	15.7%	17.1%	18.7%	20.4%	21.7%

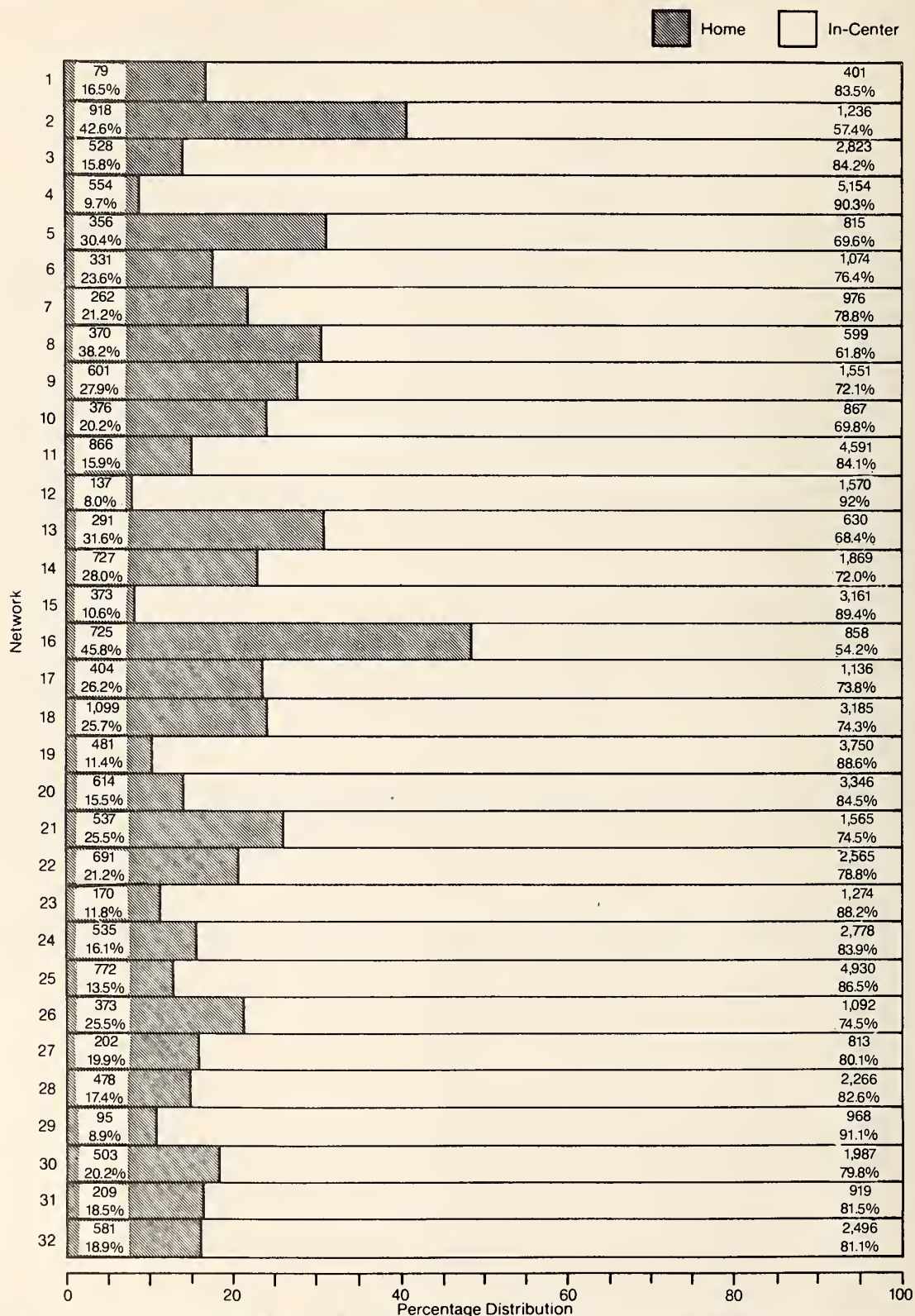
PATIENTS RECEIVING CARE AS OF 12/31/83

TABLE 4

ESRD NETWORK	FACILITIES SURVEYED & REPORTING	TOTAL PATIENTS	STAFF ASSISTED DIALYSIS		SELF-DIALYSIS IN-UNIT		SELF-DIALYSIS TRAINING		HOME PATIENTS	
			HEMO	PERI	HEMO	PERI	HEMO	PERI	HEMO	PERI
1	10	449	237	5	113	0	8	0	37	9
2	29	1,954	1,061	19	0	0	26	0	558	46
3	55	3,145	2,468	1	178	0	29	1	137	11
4	90	5,336	4,746	3	66	0	21	2	90	32
5	31	1,083	730	3	20	0	1	0	195	11
6	32	1,266	929	0	61	0	2	0	48	7
7	27	1,128	896	4	0	0	1	0	126	11
8	18	890	587	6	0	0	6	1	68	27
9	34	1,971	1,321	2	71	0	15	1	201	9
10	37	1,120	774	29	1	0	3	0	65	27
11	76	5,145	4,122	39	140	0	29	4	213	86
12	41	1,507	1,346	8	5	0	8	0	23	11
13	21	788	494	15	31	0	2	0	48	5
14	34	2,361	1,612	75	32	0	13	7	118	38
15	63	3,315	2,767	74	161	0	17	0	74	14
16	13	1,496	754	0	0	0	14	0	209	1
17	24	1,396	993	22	21	0	4	0	51	7
18	71	3,929	2,863	6	2	0	16	3	353	66
19	79	3,814	3,385	10	13	0	3	0	71	19
20	62	3,518	2,888	24	68	0	7	1	149	39
21	21	1,864	1,370	0	0	0	6	1	160	68
22	50	3,031	2,266	83	22	0	1	2	114	31
23	25	1,389	1,170	9	37	0	6	0	32	0
24	62	3,013	2,418	16	71	3	15	3	124	45
25	66	5,155	4,301	96	32	0	30	0	329	9
26	24	1,388	937	14	72	0	15	2	114	20
27	16	974	738	12	21	0	2	0	26	0
28	36	2,542	2,047	25	34	0	12	0	170	40
29	17	920	814	22	0	0	0	0	50	11
30	47	2,229	1,699	23	33	0	8	0	131	36
31	18	1,003	732	18	52	0	15	2	58	26
32	26	2,868	2,089	79	118	0	44	3	181	28
TOTAL	1,255	71,987	55,554	742	1,475	3	379	33	4,323	790
							156*			8,532

NUMBER OF PATIENTS IN EACH DIALYSIS TREATMENT SETTING BY NETWORK — 1983

Figure 7
Number of Patients in Each Dialysis Treatment Setting By Network—1984

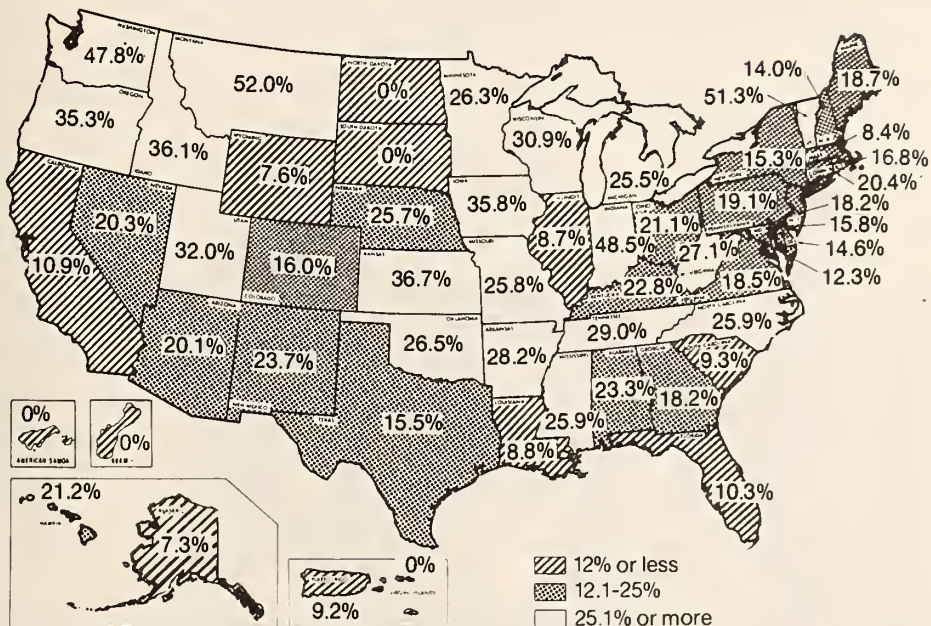


SOURCE: ESRD Medical Information System 1984 Facility Surveys

HOME DIALYSIS PATIENTS - 1983

Figure 8

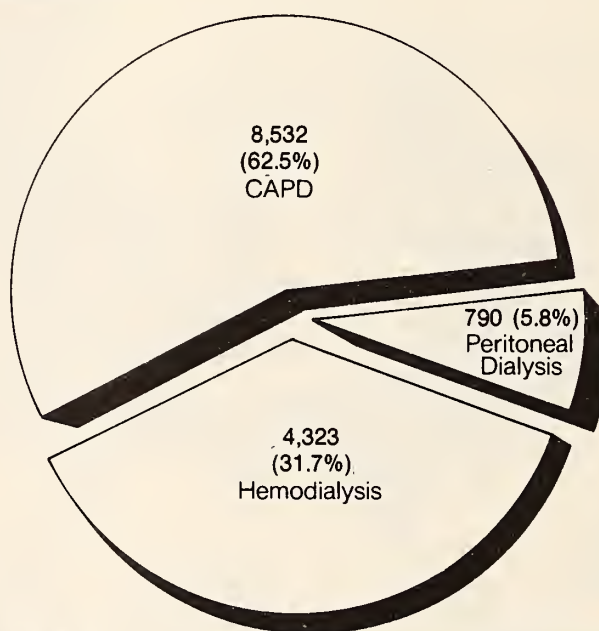
Home Dialysis Patients—1983



Source: ESRD Medical Information System 1983 Facility Surveys

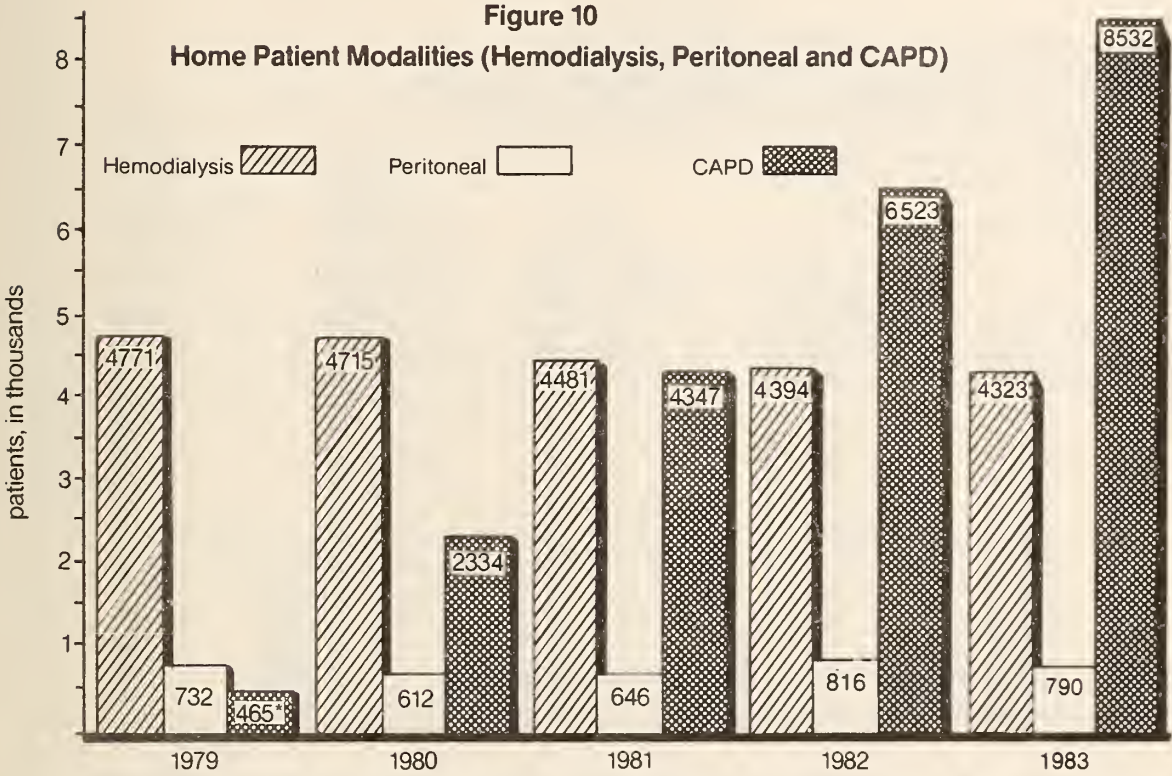
Figure 9

Home Dialysis Modality—1983



SOURCE: ESRD Medical Information System 1983 Facility Surveys .

HOME PATIENT MODALITIES (HEMODIALYSIS, PERITONEAL AND CAPD)



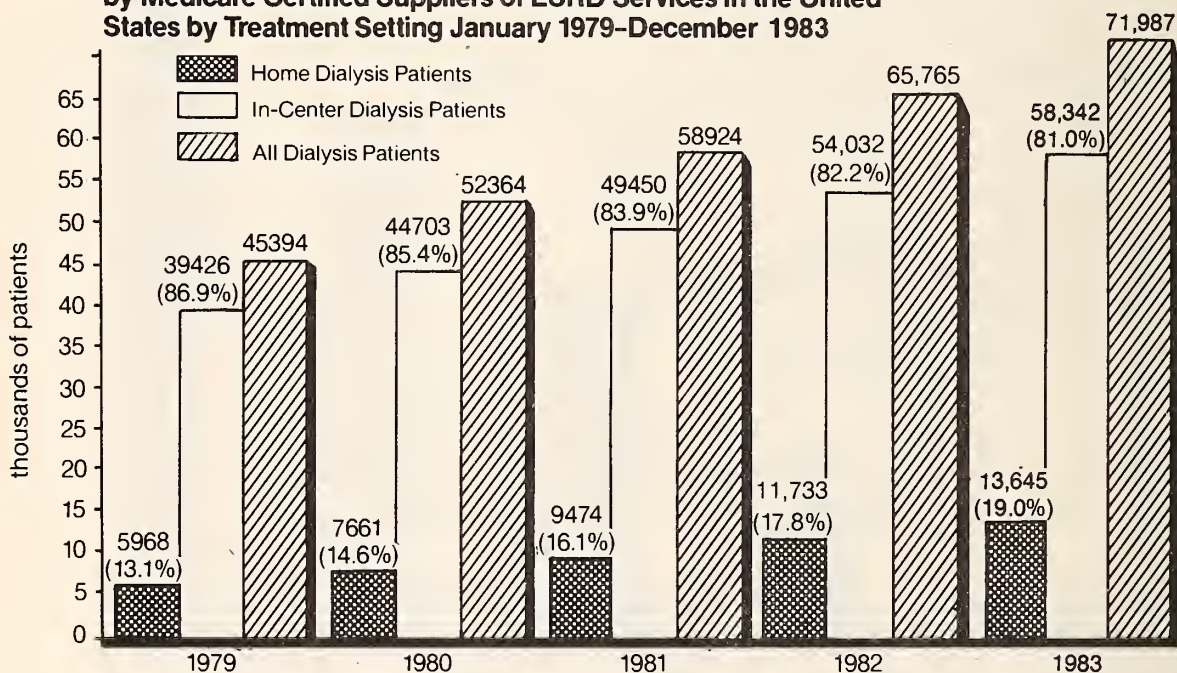
SOURCE: ESRD Medical Information System 1979, 1980, 1981, 1982 and 1983 Facility Surveys

*Payment began for CAPD in 9/79. Reportings for CAPD probably misrepresented as "Peritoneal."

**NUMBER OF CHRONIC DIALYSIS PATIENTS BEING TREATED BY MEDICARE CERTIFIED
SUPPLIERS OF ESRD SERVICES IN THE UNITED STATES BY TREATMENT SETTING
JANUARY 1979 - DECEMBER 1983**

Figure 11

**Number of Chronic Dialysis Patients Being Treated
by Medicare Certified Suppliers of ESRD Services in the United
States by Treatment Setting January 1979-December 1983**



SOURCE: ESRD Medical Information System 1979, 1980, 1981, 1982 and 1983 Facility Surveys

B. NEW PATIENT CHARACTERISTICS

See Table 5 and Figure 12

TOTAL

The total dialysis population increased by 6,222 patients from 65,765 in 1982 to 71,987 in 1983. This is an increase of 9.5 percent.

INCENTER

The incenter dialysis population increased by 4,310 which is an increase of 7.9 percent. However, the proportion of the total dialysis population represented by incenter dialysis patients decreased from 82.2 percent in 1982 to 81.0 percent in 1983.

HOME

The home dialysis population increased by 1,912, which is an increase of 16.4 percent. The portion of the total dialysis population represented by home dialysis patients increased from 17.8 percent in 1982 to 19.0 percent in 1983.

NEW STARTS

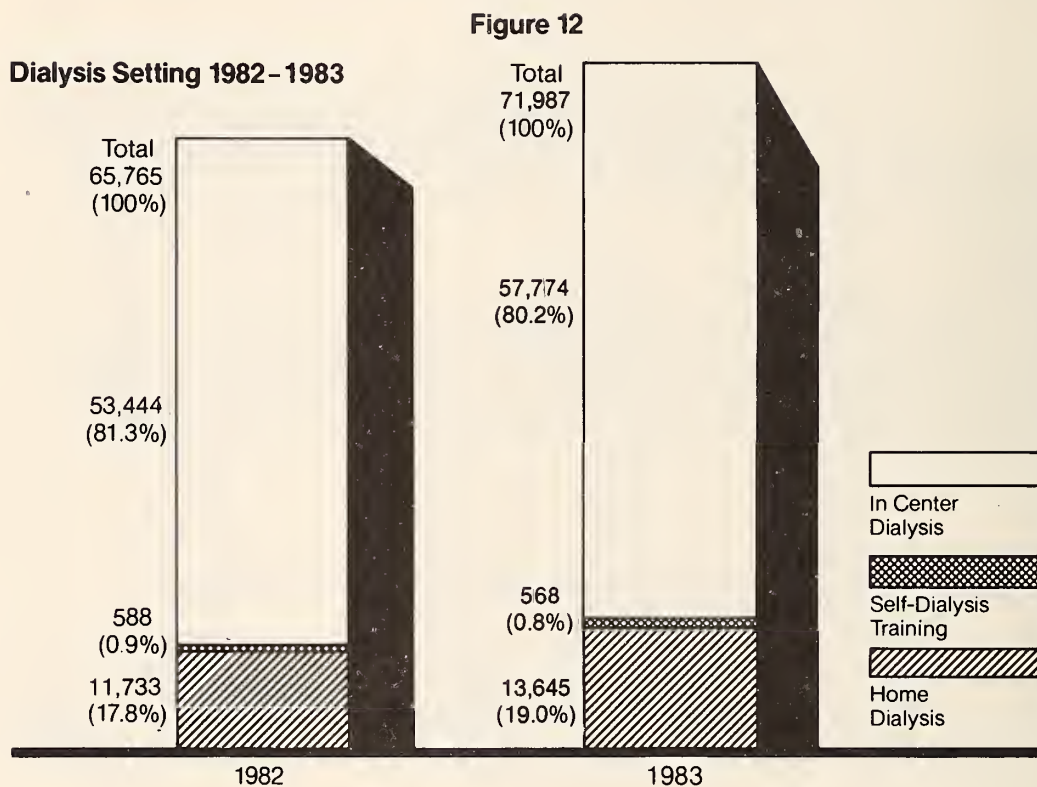
Of the 24,272 patients starting a course of dialysis for the first time ever during 1983, 3,210 (13.2 percent), chose home dialysis and 21,062 (86.8 percent), chose incenter dialysis. Comparable figures for 1982 were 2,699 (11.8 percent), of the new starts choosing home dialysis and 20,098 (88.2 percent), choosing incenter dialysis.

TABLE 5.

NUMBER AND PERCENT INCREASE OF DIALYSIS PATIENTS

	<u>1982</u>	<u>1983</u>	<u>Increase</u>	<u>Percent Increase</u>
Total Dialysis Population	65,765	71,987	6,222	9.5%
Incenter Dialysis Population	54,032	58,342	4,310	8.0%
Home Dialysis Population	11,733	13,645	1,912	16.3%

DIALYSIS SETTING 1982 - 1983



SOURCE: ESRD Medical Information System 1982 and 1983 Facility Surveys

C. CONTINUOUS AMBULATORY PERITONEAL DIALYSIS NATIONAL PATIENT REGISTRY

One of the research objectives of the Chronic Renal Disease Program of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases continues to be directed towards improving the effectiveness as well as minimizing complications of maintenance therapies for end-stage renal disease. As part of the Program's effort to evaluate and improve such therapies, the Institute has sponsored the development and initial operation of a registry for patients being maintained on Continuous Ambulatory Peritoneal Dialysis (CAPD). Objectives of the registry are to obtain and disseminate information regarding efficacy and safety, as well as associated risks of CAPD. Specifically, basic information regarding patient characteristics, primary renal disease, time on dialysis, complications -- such as peritonitis, exit site and tunnel infections -- catheter replacement, frequency of hospitalizations, transfer to other maintenance therapies, morbidity and mortality, is obtained. Data from the registry are made available to investigators and clinicians for the evaluation of CAPD.

In 1980 the CAPD Advisory Committee to NIH recommended that the Chronic Renal Disease Program initiate a registry of CAPD patients. One of the primary reasons for this recommendation was the lack of availability of data on such patients from other sources. The committee recommended the NIH operation of a CAPD registry over a limited time period as an interim measure to assemble information to assist in the evaluation of this maintenance therapy.

The registry began collecting information on a pilot basis in January of 1981. By the last quarter of 1981, 184 centers had entered the program. By the end of the second quarter of 1983, 259 centers were providing patients' follow-up information. By that time, the registry had received registration forms for a total of 8,075 patients ---7,734 on CAPD and 341 on CCPD (Continuous Cycling Peritoneal Dialysis) -- with follow-up information available on 6,706 patients.

The initial operation of the registry has been conducted through a contract with the University of Missouri which housed the Clinical Coordinating Center and it included a subcontract with the University of Texas, Austin, for operation of the Data Coordinating Center. In FY 83, competitive bidding for both the contract and subcontract was held and, as a result, the registry is now managed by the Clinical Coordinating Center which remained at the University of Missouri-Columbia, and a Coordinating Center which is located at the EMMES Corporation in Potomac, Maryland. The Clinical Coordinating Center is a liaison between the Registry and the medical community, and specifically assists in new center recruitment and information dissemination. The primary mission of the Data Coordinating Center is to operate the data collection and processing system, provide epidemiological and biostatistical support, and produce technical reports in collaboration with the Clinical Coordinating Center.

CHAPTER IV

TRANSPLANT

A. SUMMARY OF TRANSPLANT ACTIVITY
See Table 6 and Figures 13, 14, and 15

During 1983, 6,112 kidney transplants were performed. This represents an increase of 754 transplants, or 14.0 percent, over the 5,358 transplants performed in 1982. The number of living related donor transplants in 1983 was 1,784, an increase of 107 (6.3 percent) such transplants over the 1982 figure of 1,677. Cadaveric transplants, on the other hand, increased by 647 (17.6 percent) to 4,328 from 3,681 such transplants in 1982.

B. TRANSPLANTS PERFORMED DURING 1983 - BY STATE

ESRD MEDICAL INFORMATION SYSTEM - FACILITY SURVEY TABLES

TRANSPLANTS PERFORMED DURING 1983 - BY STATE

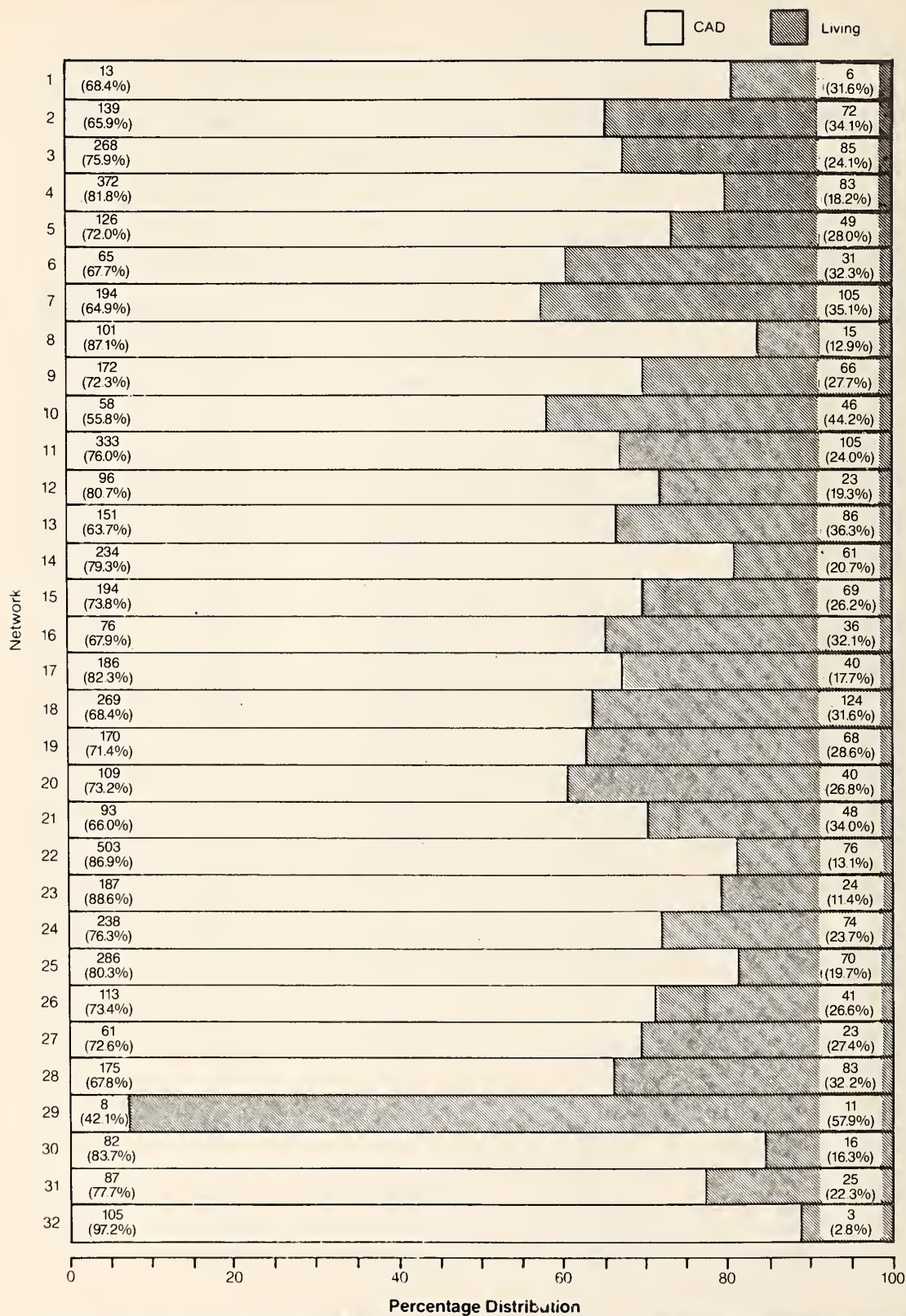
Table 6

<u>STATE</u>	<u>FACILITIES SURVEYED & REPORTING</u>	<u>TOTAL PATIENTS</u>	<u>TOTAL TRANSPLANTS</u>	<u>LIVING DONOR</u>	<u>CADAVERIC DONOR</u>
Alabama	2	164	164	68	96
Arizona	3	94	94	29	65
Arkansas	2	17	17	13	4
California	13	727	729	177	552
Colorado	1	44	44	2	42
Connecticut	2	78	79	24	55
Washington DC	5	159	160	33	127
Florida	4	195	195	72	123
Georgia	4	90	90	36	54
Hawaii	1	20	20	4	16
Illinois	7	229	229	71	158
Indiana	2	90	90	32	58
Iowa	2	59	59	17	42
Kansas	2	42	42	5	37
Kentucky	2	73	73	18	55
Louisiana	5	85	85	24	61
Maine	1	18	18	3	15
Maryland	3	70	71	16	55
Massachusetts	7	272	273	98	175
Michigan	10	256	256	50	206
Minnesota	3	297	297	126	171
Mississippi	1	24	24	0	24
Missouri	6	156	156	56	100
Nebraska	1	32	33	0	33
New Jersey	3	71	71	7	64
New Mexico	1	18	18	15	3
New York	13	437	440	94	346
North Carolina	5	159	160	48	112
Ohio	9	435	436	133	303
Oklahoma	4	55	55	17	38
Oregon	1	95	95	36	59
Pennsylvania	8	383	385	65	320
Puerto Rico	2	22	22	22	0
South Carolina	1	38	38	13	25
Tennessee	2	192	192	70	122
Texas	7	408	408	136	272
Utah	3	28	28	18	10
Vermont	1	22	22	10	12
Virgin Island	1	5	5	3	2
Virginia	4	106	106	13	93
Washington	4	91	91	31	60
Wisconsin	2	242	242	79	163
TOTAL	160	6,098	6,112	1,784	4,328

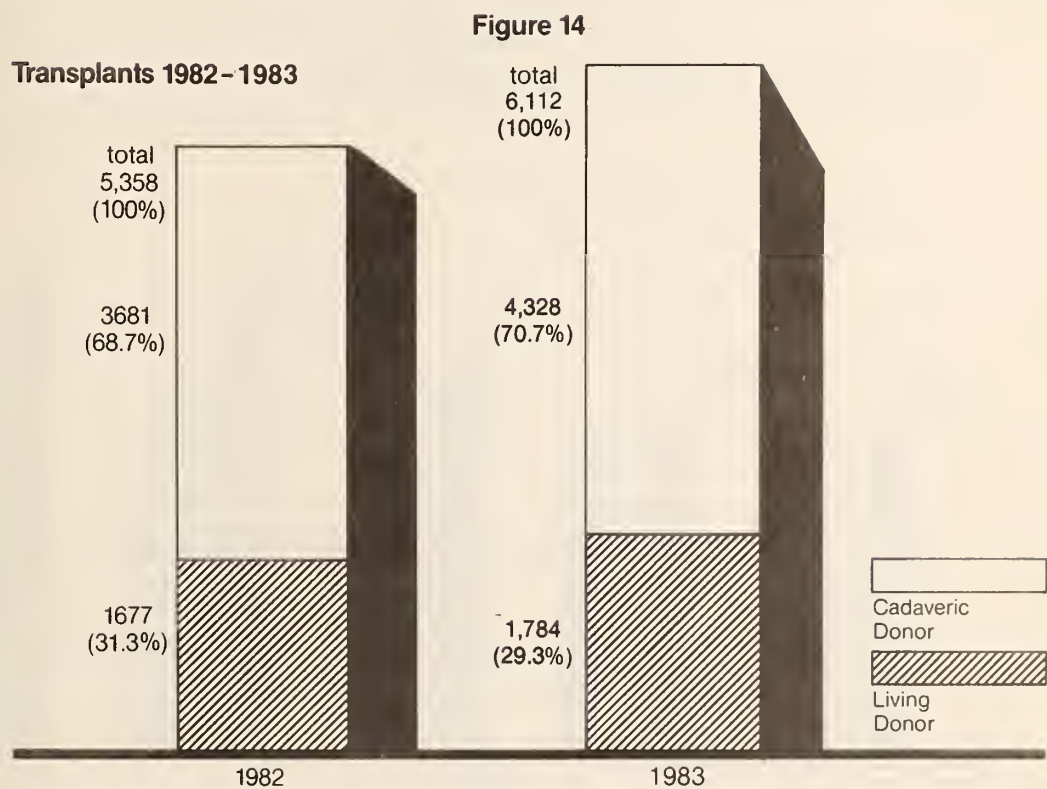
SOURCE: ESRD MEDICAL INFORMATION SURVEY 1983 FACILITY SURVEYS

Figure 13

Number Of Transplant Types by Network—1984



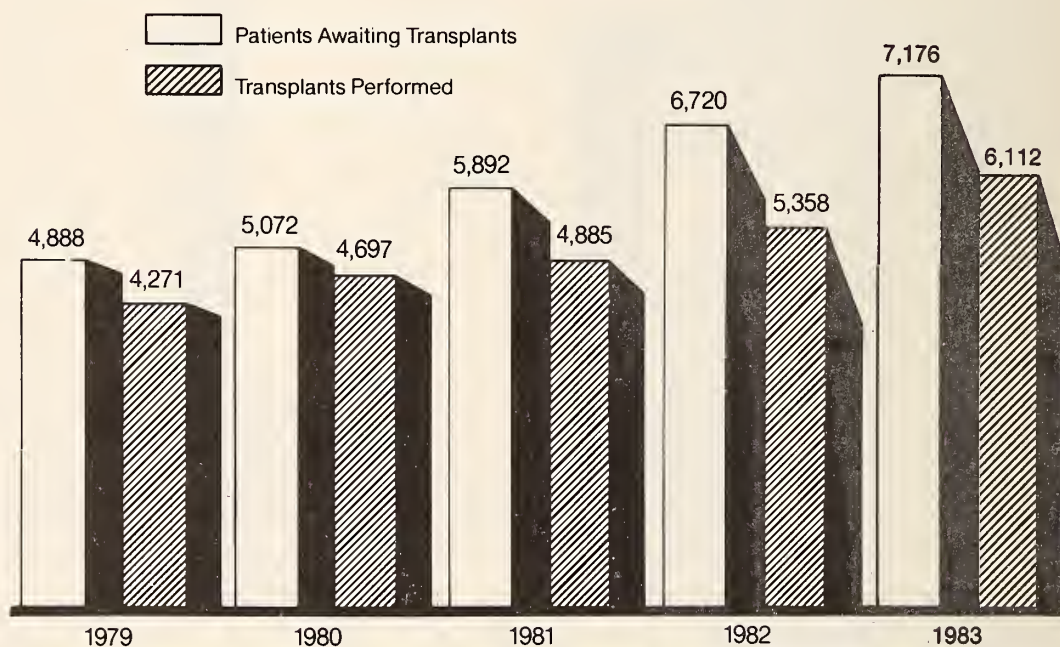
SOURCE: ESRD Medical Information System 1984 Facility Surveys



SOURCE: ESRD Medical Information System 1982 and 1983 Facility Surveys

E. PATIENTS AWAITING TRANSPLANTS VS TRANSPLANTS PERFORMED

Figure 15
Patients Awaiting Transplants vs. Transplants Performed



SOURCE: ESRD Medical Information System 1979, 1980, 1981, 1982 and 1983 Facility Surveys

F. TRANSPLANT FAILURES

Although exact information on the number of transplant failures is not available, information collected by HCFA shows that 1,867 patients returned to dialysis from transplantation during 1983. This figure represents 30.5 percent of all patients transplanted in 1983. Comparable figures for 1982 are 1,563 patients, or 29.3 percent of all patients transplanted in 1982.

However, it is important to note that these figures do not present a complete picture of transplant failures. For example, it is impossible to tell from these figures how many years a transplanted graft functioned before failing, since patients returning to dialysis for transplantation in 1983 may have received their transplant several years earlier. Further, data collected from ESRD facilities does not capture transplant failures which resulted in death.

More detailed analyses of graft survival rates are presented in the section on mortality and graft failure rates.

G. RANGE OF THE NUMBER OF TRANSPLANTS PERFORMED

The table below shows the range of the numbers of transplants performed, as reported by the hospitals, for 1983. Table 8 provides a more detailed breakdown.

TABLE 7.

RANGE OF THE NUMBERS OF TRANSPLANTS PERFORMED FOR 1983

<u>Range of Numbers of Transplants Performed</u>	<u>Number of Centers</u>	<u>Percent</u>
0-6	15	9.4
7-14	20	12.5
15-24	40	25.0
25-49	45	28.1
50 or more	40	25.0

H. ESRD NETWORK DISTRIBUTION OF TRANSPLANTS PERFORMED

ESRD NETWORK DISTRIBUTION OF TRANSPLANTS
ARRAYED BY NUMBER OF TRANSPLANTS PERFORMED

TABLE 8.

ESRD NETWORK		FACILITIES		TRANSPLANTS		ESRD NETWORK DISTRIBUTION OF TRANSPLANTS					ESRD NETWORK DISTRIBUTION OF TRANSPLANTS				
		SURVEYED-REPORTED				ARRAYED BY NUMBER OF TRANSPLANTS PERFORMED					ARRAYED BY NUMBER OF TRANSPLANTS PERFORMED				
						0	THRU 6	7	THRU 14	15	THRU 24	25	THRU 49	50	OR MORE
1	1	20	0	0.0%	0	0.0%	0	0.0%	1	100.0%	0	0.0%	0	0.0%	
2	5	186	0	0.0%	2	40.0%	1	20.0%	1	20.0%	1	20.0%	1	20.0%	
3	2	290	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	2	100.0%	
4	11	439	0	0.0%	1	9.1%	4	36.4%	4	36.4%	4	36.4%	2	18.2%	
5	4	72	2	50.0%	0	0.0%	0	0.0%	0	0.0%	2	50.0%	0	0.0%	
6	4	112	1	25.0%	0	0.0%	2	50.0%	2	50.0%	0	0.0%	1	25.0%	
7	3	297	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	3	100.0%	
8	3	92	1	33.3%	0	0.0%	0	0.0%	0	0.0%	1	33.3%	1	33.3%	
9	8	198	1	12.5%	0	0.0%	1	12.5%	1	12.5%	6	75.0%	0	0.0%	
10	6	72	1	16.7%	2	33.3%	3	50.0%	3	50.0%	0	0.0%	0	0.0%	
11	7	408	0	0.0%	0	0.0%	1	14.3%	0	0.0%	1	14.3%	5	71.4%	
12	5	85	2	40.0%	1	20.0%	0	0.0%	0	0.0%	2	40.0%	0	0.0%	
13	2	242	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	2	100.0%	
14	10	256	1	10.0%	3	30.0%	1	10.0%	1	10.0%	4	40.0%	1	10.0%	
15	7	229	2	28.6%	1	14.3%	0	0.0%	0	0.0%	3	42.9%	1	14.3%	
16	2	90	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	50.0%	1	50.0%	
17	6	167	0	0.0%	1	16.7%	1	16.7%	3	50.0%	1	16.7%	1	16.7%	
18	5	380	0	0.0%	1	20.0%	1	20.0%	1	20.0%	0	0.0%	3	60.0%	
19	4	195	0	0.0%	0	0.0%	0	0.0%	0	0.0%	2	50.0%	2	50.0%	
20	5	128	1	20.0%	1	20.0%	1	20.0%	0	0.0%	2	40.0%	1	20.0%	
21	5	160	0	0.0%	0	0.0%	0	0.0%	2	40.0%	3	60.0%	0	0.0%	
22	6	502	0	0.0%	0	0.0%	0	0.0%	2	33.3%	0	0.0%	4	66.7%	
23	5	160	0	0.0%	0	0.0%	0	0.0%	3	60.0%	0	0.0%	2	40.0%	
24	7	225	0	0.0%	1	14.3%	1	14.3%	3	42.9%	2	28.6%	1	14.3%	
25	7	307	0	0.0%	1	14.3%	1	14.3%	2	28.6%	2	28.6%	2	28.6%	
26	6	133	1	16.7%	1	16.7%	1	16.7%	3	50.0%	0	0.0%	1	16.7%	
27	2	79	0	0.0%	0	0.0%	0	0.0%	0	0.0%	2	100.0%	0	0.0%	
28	9	313	0	0.0%	1	11.1%	1	11.1%	4	44.4%	1	11.1%	3	33.3%	
29	3	27	2	66.7%	0	0.0%	0	0.0%	1	33.3%	0	0.0%	0	0.0%	
30	4	106	0	0.0%	1	25.0%	1	25.0%	1	25.0%	2	50.0%	0	0.0%	
31	3	71	0	0.0%	1	33.3%	1	33.3%	1	33.3%	1	33.3%	0	0.0%	
32	3	71	0	0.0%	1	33.3%	1	33.3%	0	0.0%	2	66.7%	0	0.0%	
TOTAL		160	15	9.4%	20	12.5%	40	25.0%	45	28.1%	40	25.0%	40	25.0%	
NATIONAL TOTAL				9.4%		21.9%		46.9%		75.0%		100.0%		100.0%	

PERCENTAGES MAY NOT ADD TO 100.0% DUE TO ROUNDING

SOURCE: ESRD MEDICAL INFORMATION SYSTEM 1983 FACILITY SURVEY

CHAPTER V

COST

A. HOSPITALIZATION FOR ANCILLARY PROBLEMS

For the purposes of this report, ancillary hospitalizations were defined as all hospitalizations other than transplants. This is a necessary simplification because many hospitalizations are related to the transplant event, either before the actual transplant or afterward, such as rejection episodes. On average, each transplant patient is hospitalized about three times during the year in which he receives his transplant. However, it is not possible to completely identify which hospital stays are transplant "related." Therefore, the nontransplant stays of transplant patients are considered to be ancillary hospitalizations.

DATA

The basic data were taken from the 1981 MEDPAR* 20 percent sample of hospital stays. This sample of stays includes procedure coding so it was possible to determine average charges and length of stay for transplant and nontransplant stays. The 1981 MEDPAR contained a slight shortfall (about one percent) at the time of this analysis. Thus, the figures were adjusted upward to approximate costs for 100 percent of stays. Hospital covered charges and covered days of care were estimated directly from the MEDPAR records.

Program costs in the form of actual Medicare reimbursements were calculated by taking the national Medicare reimbursement to charges ratio and applying it to these discharges.

RESULTS

Table 9 summarizes the results of this analysis. In 1981, Medicare ESRD patients had a total of 106,899 discharges. Of the total discharges, 58 percent were nonsurgical, 38 percent included a surgical procedure other than transplant, and the remaining 4 percent were for transplants.

Inpatient charges amount to over \$602 million for this population. Because of the relatively high cost of transplant stays, one-fifth (20 percent) of all inpatient charges were for transplant stays. Overall, the average charge per stay for the ESRD population in 1981, was \$5,628. The average transplant stay had a charge of \$26,730 while the average ancillary (i.e., nontransplant) hospital stay had a charge of \$4,718. Of the total ancillary stays, the average charge for nonsurgical stays was \$3,032 and the average charge for surgical stays was \$7,314.

Medicare reimbursements are not equal to hospital charges. Applying the national ratio of Medicare reimbursements to charges gives an estimate of the costs to Medicare for ESRD hospitalization. In 1981 the cost to charges ratio was .687. That is, Medicare paid hospitals an average of 68.7 percent of charges. An exception to this is kidney acquisition costs, which are reimbursed at 100 percent. For all ESRD patients, estimated Medicare inpatient hospital payments were \$426 million: \$94 million for transplants, and \$332 million for nontransplant (or ancillary) stays.

*Medicare Provider Analysis and Review File, which is a random 20 percent sample of all inpatient discharges. It includes diagnostic and procedure coding.

As noted earlier, nonsurgical stays comprised 58 percent of all stays while the nontransplant surgical stays were 38 percent of the total. However, due to the higher costs of surgical stays, the nontransplant surgical stays accounted for 62 percent of all nontransplant stays (48 percent of all reimbursements). The estimated Medicare reimbursements per stay are \$3,989 for all discharges, \$21,326 for transplants and \$3,241 for all nontransplant stays.

Table 9

CHARGES, ESTIMATED REIMBURSEMENTS AND
AVERAGE LENGTH OF STAY FOR TRANSPLANT AND
NONTRANSPLANT HOSPITAL STAYS: 1981

	All Stays	Transplant Stays	All	<u>Nontransplant Stays</u>	
				Non- Surgical	Surgical
Number of Stays	106,899	4,421	102,478	62,139	40,339
Percent	100%	4%	96%	58%	38%
Charges (in 1,000's)	\$ 601,628	\$118,173	\$ 843,455	\$188,416	\$295,039
Percent	100%	20%	80%	31%	40%
Charges Per Stay	\$ 5,628	\$ 26,730	\$ 4,718	\$ 3,032	\$ 7,314
Estimated Reimbursement (1,000's)	\$ 426,417	\$ 94,284	\$ 332,133	\$129,442	\$202,691
Percent	100%	22%	78%	30%	48%
Estimated Reimbursement Per Stay	\$ 3,989	\$ 21,326	\$ 3,241	\$ 2,083	\$ 5,025
Covered Days	1,203,574	125,556	1,078,018	598,697	479,321
Percent	100%	10%	90%	50%	40%
Average Length of Stay (Covered Days)	11.3	28.4	10.5	9.6	11.9

SOURCE: 1981 MEDPAR 20 PERCENT SAMPLE OF HOSPITAL STAYS

B. KIDNEY ACQUISITION COSTS

Kidney acquisition services are those services necessary to identify potential donors, maintain a registry of patients awaiting transplant, ensure suitability and compatibility of the selected donor and recipient, excise the donor kidney, transport the organ to the transplant hospital, and maintain the viability of the organ until the time of transplantation. The charges for these services are accumulated and billed to the Medicare program by the hospital which performs the transplant.

The information available on kidney acquisitions is charge data rather than actual cost information. Charge data are received as individual bills and are recorded when the bills are submitted to the intermediary. Cost data are not available until final settlement of each hospital's audited cost report for the fiscal year in question.

In order to determine kidney acquisition charges for 1983, the DHHS Regional Offices requested the intermediaries to provide their transplant hospitals' charges in effect as of December 31, 1983, for living related donor kidneys and cadaveric donor kidneys. This information was provided for 143 transplant hospitals. HCFA compiled the data and found that during 1983, the national average kidney acquisition charge for a living related donor kidney was \$10,065 and for cadaveric donor kidneys it was \$9,850. The range and average of kidney acquisition charges by DHHS Regions are shown in Tables 10A and 11A.

The intermediaries were also requested to report for each transplant center the total cost to charges ratio from the settled or filed cost reports for the three most recent years. To convert charge data to estimated costs, we multiplied the charges by the Medicare cost to charge ratio. The calculations result in an average estimated national kidney acquisition cost for living related donor kidneys of \$8,452; and for cadaveric donor kidneys the average estimated costs were \$8,298. The range and average of estimated kidney acquisition costs by DHHS Region are shown in Tables 10B and 11B.

It should be noted that the costs derived are based on the arithmetic mean, and are not weighted by the number of transplants performed in each hospital.

TABLE 10A.

KIDNEY ACQUISITION CHARGES
AVERAGE AND RANGE FOR LIVING RELATED
DONOR KIDNEYS FOR 1983 BY REGION

<u>REGION</u>	<u>HIGH</u>	<u>LOW</u>	<u>AVERAGE</u>
Boston	\$17,500	\$2,000	\$11,035
New York	15,000	2,400	7,917
Philadelphia	24,750	6,000	11,595
Atlanta	20,240	4,500	8,709
Chicago	20,500	3,000	10,510
Dallas	14,000	3,000	8,046
Kansas City	23,075	10,900	14,572
Denver	9,946	4,112	7,019
San Francisco	14,208	5,387	9,688
<u>Seattle</u>	<u>16,849</u>	<u>8,850</u>	<u>11,560</u>
National	\$17,607	\$5,015	\$10,065

TABLE 10B.

KIDNEY ACQUISITION COSTS
AVERAGE AND RANGE OF ESTIMATED COSTS FOR LIVING RELATED
DONOR KIDNEYS FOR 1983 BY REGION

<u>REGION</u>	<u>HIGH</u>	<u>LOW</u>	<u>AVERAGE</u>
Boston	\$12,308	\$1,654	\$ 8,720
New York	14,652	1,977	6,841
Philadelphia	21,800	3,640	8,673
Atlanta	18,086	3,647	7,775
Chicago	18,094	2,767	8,748
Dallas	11,379	3,562	6,957
Kansas City	18,520	7,437	12,408
Denver	9,258	3,622	6,379
San Francisco	14,814	4,081	8,326
<u>Seattle</u>	<u>13,437</u>	<u>6,813</u>	<u>9,696</u>
National	\$15,235	\$3,920	\$ 8,452

Source: Medicare Fiscal Intermediaries' Reimbursement Files

TABLE 11A.

KIDNEY ACQUISITION CHARGES
AVERAGE AND RANGE FOR CADAVERIC DONOR KIDNEYS
FOR 1983 BY REGION

<u>REGION</u>	<u>HIGH</u>	<u>LOW</u>	<u>AVERAGE</u>
Boston	\$14,000	7,800	10,275
New York	15,000	2,400	8,300
Philadelphia	24,750	6,300	10,386
Atlanta	13,925	3,500	8,092
Chicago	19,400	3,000	10,163
Dallas	10,700	1,500	7,720
Kansas City	24,000	8,730	15,956
Denver	8,547	4,100	6,323
San Francisco	15,700	8,000	10,257
<u>Seattle</u>	<u>16,849</u>	<u>8,100</u>	<u>11,030</u>
National	\$16,287	\$5,343	\$ 9,850

TABLE 11B.

KIDNEY ACQUISITION COSTS
AVERAGE AND RANGE OF ESTIMATED COSTS FOR CADAVERIC
DONOR KIDNEYS FOR 1983 BY REGION

<u>REGION</u>	<u>HIGH</u>	<u>LOW</u>	<u>AVERAGE</u>
Boston	\$11,130	\$5,343	\$ 8,175
New York	14,652	1,977	7,134
Philadelphia	21,800	3,640	7,794
Atlanta	12,988	3,064	7,194
Chicago	18,094	2,551	8,526
Dallas	9,527	4,470	6,871
Kansas City	20,316	7,079	13,538
Denver	7,956	3,665	5,810
San Francisco	16,564	5,614	8,895
<u>Seattle</u>	<u>13,437</u>	<u>6,531</u>	<u>9,046</u>
National	\$14,646	\$4,393	\$ 8,298

TABLE 12. 1983 KIDNEY ACQUISITION COSTS
REPORTED BY INDEPENDENT ORGAN PROCUREMENT AGENCIES
BY REGION

<u>REGION</u>	<u>COST PER KIDNEY</u>
Boston	\$ 7,107
New York	1,793* 6,846 9,905
Philadelphia	1,824 4,017 6,522** 8,631
Atlanta	0 (no activity) 2,358** 2,859 3,627 5,959 7,864** 9,402 11,847 12,841
Chicago	6,436 6,821 8,560 8,581** 10,216 12,913
Dallas	8,207 8,430 8,824 18,885
Kansas City	5,897 8,665 9,858
Denver	0 (no activity)
San Francisco	4,522* 10,152
Seattle	7,938

*Limited Service OPAS

**First Year of Activity

Source: Medicare Fiscal Intermediaries' Reimbursement Files

C. INDEPENDENT ORGAN PROCUREMENT AGENCIES

Some kidney acquisition services are performed for hospitals by independent organ procurement agencies (OPAs). The services provided differ among OPAs, and range from providing only placement services, to providing all services except medical evaluation of the recipient or any living donors. The costs incurred by an OPA are billed to the transplant hospital and become a component of the hospital's kidney acquisition cost.

Independent OPAs are reimbursed on a cost basis. There were 34 operational OPAs during 1983. The cost per kidney for these OPAs ranged from \$1,793 to \$18,885. These figures are cost figures and as such are subject to adjustment on final cost settlement. The cost per kidney varies widely because of the variation in the number of kidney acquisition services performed by the individual OPAs. The data for OPAs were not broken down by type of kidney donor.

Table 12 shows the cost per kidney reported by the OPAs in each of the 10 DHHS Regions. One of the OPAs has been excluded from consideration because it is an umbrella organization, and its member OPAs are included in the data display.

D. DIALYSIS PAYMENT RATES

In 1983, there was a change in the way the Medicare program pays for outpatient dialysis services. Prior to August 1, 1983, the average payment rate for maintenance dialysis was estimated to be \$160 per treatment (includes all approved reimbursement exception requests). This payment rate reflected the combined weighted average of the payment to each of the two types of ESRD facilities: hospital-based and nonhospital (independent). Hospital-based facilities were paid the lesser of their cost or a national payment screen. Their average reimbursement rate in 1983 was estimated to be \$183 per treatment (exclusive of physicians' services). Independent facilities were paid the lesser of their charge or a national payment screen. Their average payment (exclusive of physicians' services) was estimated to be \$138 per treatment.

On May 11, 1983, the Department of Health and Human Services published final regulations implementing a change in the law enacted as part of the 1981 Omnibus Budget Reconciliation Act. That Act required that dialysis services be reimbursed under a dual, prospective, composite rate system. Under this system one rate per treatment would be set per facility and in the patient's home. The rates were set prospectively based on the relative costs of home dialysis versus infacility dialysis weighted by the percentage of patients dialyzing in each setting. The rates vary according to the geographical variations experienced in wages across the country, and separate rates were set for hospital-based facilities and independent facilities. The average payment rates were \$130.41 per treatment for hospital-based facilities and \$125.59 per treatment for independent facilities. These new regulations were effective for dialysis services performed on or after August 1, 1983.

E. EXCEPTION SYSTEM

1. Reimbursement System - Prior to August 1, 1983

Any ESRD facility desiring a payment rate above the national payment screen of \$138 had to request a reimbursement exception and submit documentation of its higher costs in accordance with instructions set forth in Intermediary Letters 78-9 and 82-1. During 1983, 114 requests for reimbursement exceptions were received. We responded to 99 of these exception requests and had 15 pending as of December 31, 1983. Of the 99 responses, 49 were returned to the appropriate intermediary for further development, 39 were denied and 11 exceptions approved in part.

A breakdown of the 114 reimbursement exception requests for periods prior to August 1, 1983.

1977	1
1978	4
1979	10
1980	22
1981	56
1982	21

The top six States with the largest number of exception requests are given below. These States represent 56 percent of the total exceptions received from January 1983 through December 1983. However, they represent only 35 percent of the total number of dialysis facilities.

	<u>State</u>	<u>Exceptions Received</u>	<u>Percentage</u>
1.	Illinois	14	12
2.	Wisconsin	13	11
3.	Pennsylvania	13	11
4.	California	10	9
5.	New York	8	7
6.	Ohio	7	6
	Total	<u>65</u>	<u>56%</u>
	All other States	<u>49</u>	<u>44%</u>
		114	100%

A comparison by region of exception requests received is given below.

<u>Region</u>	<u>Dialysis Facilities</u>	<u>Exceptions Received</u>
I	52	2
II	125	10
III	161	13
IV	232	4
V	193	40
VI	163	7
VII	47	12
VIII	40	6
IX	171	17
X	24	3
	<u>1,208</u>	<u>114</u>

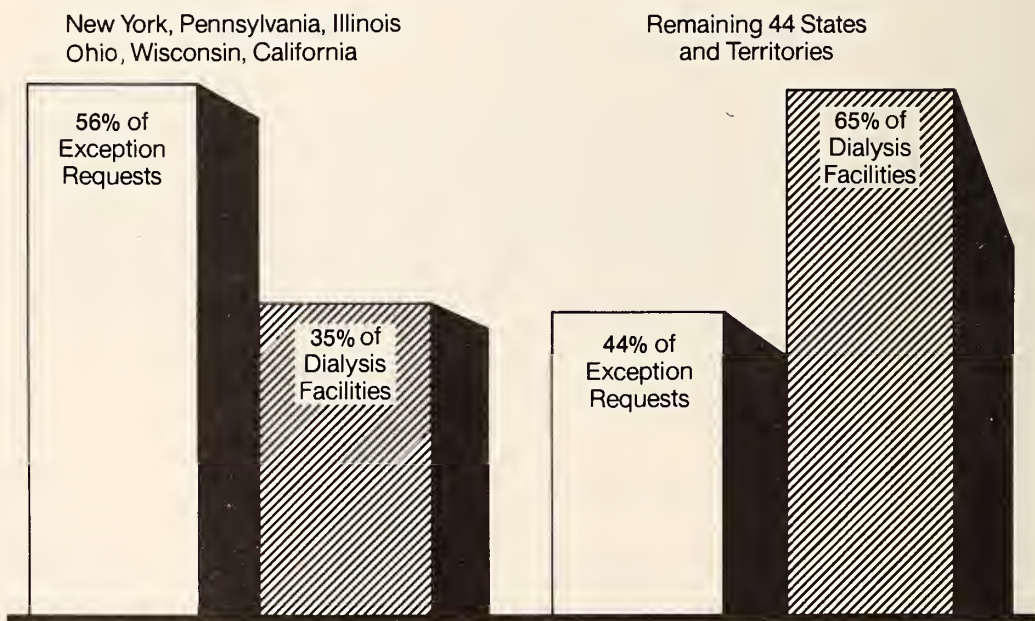
2. Composite Rate Reimbursement System - Effective August 1, 1983

Any ESRD facility desiring a payment rate above the composite rate must request a reimbursement exception within 180 days of being notified of its payment rate and submit required documentation.

During 1983, eight requests for exceptions to the composite rate were received. We responded to four of these requests and had four requests pending as of December 31, 1983. Of the four that were processed, three were returned to the intermediary for further development, and one was approved.

COMPARISON BY STATE OF EXCEPTION REQUESTS-1983

Figure 16
Comparison By State of Exception Requests— 1983



Source: Bureau of Eligibility, Reimbursement and Coverage Program Data, HCFA

F. TRANSPLANT PROCEDURES

The estimated 1981 reimbursement per stay for transplants was \$21,326. This figure is derived from the Medicare Provider Analysis and Review File, which is a random 20 percent sample of all inpatient discharges. To compute the expenditures for transplant procedures in 1983, we applied the inflation factor for Inpatient Expense per Admission for 1982 and 1983. Based on unpublished data from the Health Care Financing Administration, the inflation factor for 1982 was 15.5 percent and for 1983 was 10.2 percent. The resulting cost for a 1983 transplant procedure was \$27,144, excluding physicians' services but including the kidney acquisition cost.

G. PHYSICIANS' SERVICES

Dialysis

The method of paying for physicians' dialysis services was changed on August 1, 1983, as a result of the implementation of the Omnibus Budget Reconciliation Act of 1981. Prior to August 1, 1983, physicians' dialysis services were reimbursed under one of two methods--the initial method and the alternative method. Under the initial method, physicians received payment for their supervisory dialysis services directly from the facility, usually under a salary or contract arrangement. Other services required by the patient (not considered routine) were billed to the Medicare program by the physician on a fee-for-service basis.

Under the initial method, the payment to physicians for supervisory services during dialysis was part of the overall dialysis charge billed by the facility. Based on unaudited cost reports submitted by dialysis facilities, the average payment for physicians' supervisory services was \$13 per treatment.

Under the alternative reimbursement method, physicians were paid a monthly fee for each patient for all renal care of that patient. This included supervisory services during dialysis, plus all other renal-related services, complicated or routine, furnished during a particular month.

The alternative monthly allowances for physician services to patients dialyzing in a facility ranged from a minimum level of \$180 to a maximum level of \$260. The allowances for physician services for treatment of patients dialyzing in the home ranged from a minimum level of \$126 to a maximum level of \$182. The lower payment rates for home dialysis are due to the fewer services rendered to home dialysis patients.

After August 1, 1983, the initial method of reimbursement was eliminated and the alternative reimbursement method was modified to become the monthly capitation payment (MCP) method. These changes were made in response to a requirement in the 1981 legislation (Omnibus Budget Reconciliation Act of 1981) that physician reimbursement promote efficiency and increased use of home dialysis.

The MCP method is similar to the alternative reimbursement method in that it is a comprehensive monthly payment for all renal-related services for each dialysis patient. The major difference is that the same rate is paid for patients who are

treated in a facility and for patients who are treated at home. A second difference is that the monthly payment is based on the local charges for internists' services in each of 260 localities across the country. The alternative reimbursement method payment varied by the 70 carrier service areas across the country. Therefore, the new MCP more accurately reflects the local charging practices of physicians in the immediate geographical area. Also, the basis for setting the MCP is different from the basis for setting the alternative reimbursement method monthly payment. The payment levels under the MCP range from a minimum of \$144 per month to a maximum of \$220 per month. The MCP is expected to fulfill the statutory requirement of promoting home dialysis because the same rate is paid for home dialysis and in-facility dialysis. Home dialysis requires less physician involvement and time; therefore, the reward per time spent treating home patients is greater.

Physician payments are subject to the Supplementary Medical Insurance (Part B) deductible and coinsurance and, thus, Medicare reimbursement is made for 80 percent of the MCP rate.

Transplant

The rules used to determine payment for physicians' renal transplantation services are different from the regular Medicare reasonable charge methodology used to determine payment for physicians' services. Under the regular methodology, the carrier determines the customary charge (generally, the charge most frequently made) by each physician for each separate service furnished to patients in the previous calendar year. The carrier determines the prevailing charge for each covered service. The prevailing charge is the amount which is high enough to cover the customary charges in three out of every four bills submitted in the previous year for each service. Increases in prevailing charges for physicians' services are limited from year to year by an "economic index" formula which relates physicians' fee increases to the actual increases in the cost of maintaining their practices and to raises in general earnings levels.

When a medical insurance claim is submitted, the carrier compares the actual charge shown on the claim with the customary and prevailing charges for that service. The charge approved by the carrier will be either the customary charge, the prevailing charge, or the actual charge, whichever is the lowest.

With respect to renal transplantation services, a comprehensive payment is made for all of the surgeon's services including the usual pre and postoperative surgical care, and for immunosuppressant therapy, when supervised by the attending transplant surgeon, for a period of 60 days. Additional amounts established on the basis of program experience may be included for other surgery performed concurrently with the transplant operation, such as a splenectomy, or a combination of all of these.

The comprehensive payments are revised July 1 of each year to the extent permitted by the lesser of: (1) changes in the economic index (an increase of 5.85 percent for the period July 1983-June 1984); or (2) changes from one year to the next in the prevailing charges for a unilateral nephrectomy for each of the carrier's localities.

These amounts reflect geographical variations in physician charging practices and would also vary on the basis of whether the surgeon performs other surgical procedures at the time of the renal transplantation.

H. PROJECTED ENROLLMENT AND BENEFIT PAYMENTS FOR THE END-STAGE RENAL DISEASE PROGRAM

Medicare enrollment for persons with ESRD is projected to increase from 83,700 in fiscal year 1984 to about 92,200 by fiscal year 1989. Medicare benefit payments for these persons are projected to increase from \$2.3 billion to about \$3.2 billion for the same period of time. The year-to-year changes are the result of the interaction of two factors: (1) increases in the population, including changes in the mix of treatment modes; and (2) increases in the cost of services provided. The table below shows the projected enrollment and benefit payments on a cash basis through fiscal year 1989. These projections reflect the cost effects of the newest ESRD regulations (i.e., the dual-composite rate regulation and the ESRD second-payer regulation).

TABLE 13.

ESTIMATED ENROLLMENT AND AGGREGATE PAYMENTS ON A CASH BASIS
TOTAL ESRD MEDICARE PROGRAM

<u>Fiscal Year</u>	<u>Average Annual Enrollment</u> (thousands)	<u>Total Benefit Payments</u> (millions)
1985	83.7	\$2,330
1986	86.7	2,544
1987	89.4	2,758
1988	91.2	2,981
1989	92.2	3,188

In addition, implementation of the ESRD second-payer regulation will generate additional income to the Medicare program. We estimate this income to be as shown below.

TABLE 14.

ESTIMATED INCOME TO MEDICARE GENERATED BY
ESRD SECOND PAYER REGULATION

<u>Fiscal Year</u>	<u>Income Generated</u> (in millions)
1985	\$25
1986	35
1987	45
1988	55
1989	55

SOURCE: Office of Financial and Actuarial Analysis, HCFA

CHAPTER VI

ESRD STATISTICS

A. END-STAGE RENAL DISEASE (ESRD) PROGRAM SURVIVAL ANALYSIS

This section describes the program experience with respect to both patient and graft survival from onset of renal failure or kidney transplant to 1 year subsequent. The analysis covers the period from January 1, 1982 through December 31, 1983. All Medicare enrollees with renal failure (first date of dialysis) occurring on or after January 1, 1982 and up to December 31, 1983 were included in the analysis of dialysis survival. The transplant survival analysis included Medicare enrollees with transplants occurring on or after January 1, 1982, and up to December 31, 1983 for whom both transplant reports and transplant followup forms were filed. The total number of persons included in the computation of dialysis patient survival rates was 34,025. The total number of transplants included in the computation of transplant survival rates was 8,708.

Data

Computation of survival rates for dialysis patients requires a date of renal onset and a date of death. Computation of survival rates for transplantation, patient and graft, requires a date of transplant and a date of death or a date of graft failure. Dates of death were taken from the Master Beneficiary Records which are maintained for all Medicare beneficiaries. The determination of renal failure onset was defined as the date of first dialysis and was taken from the patient medical evidence (HCFA-2728), outpatient dialysis record (HCFA-1483), or from the Medicare entitlement records. The date of transplant was taken from the transplant form (HCFA-2745) or the inpatient hospital bill (HCFA-1453). The date of transplant failure was taken from the Transplant Followup form.

Survival rates were calculated using a standard actuarial modified life-table analysis. For each interval (each successive 6 months following renal onset (dialysis) or transplant), the number of deaths occurring during the interval was divided by the number of persons at risk during the interval to obtain the survival rate.

Results

Table 15 presents the results of the survival analysis for all Medicare persons with ESRD treated by dialysis. Because Medicare entitlement occurs for many persons following a 90-day waiting period, survival probabilities were computed beginning from the end of this waiting period. Eight-nine (89) percent of all persons survived for an additional 6 months and 81 percent 1 year. There is no difference in survival rates between males and females. This finding is true of both intervals (6 months = 89 percent, and 1 year = 81 percent). The survival rate is slightly higher for the black population on dialysis than for whites both at the 6-month and 1-year intervals. The black population survival rate after 1 year is 85 percent; the white population survival rate is 79 percent. Survival rates are better for the younger population. Those 30 years of age and younger have survival rates of 90 percent or higher. Those 31-50 years of age have survival rates from low to high 80's. From age 60 to 70, the survival rates fall to the mid-70's; and this trend continues with ages 70+ having a survival rate in the mid-60's. The primary disease responsible for kidney failure appears to have a significant bearing on survival. Where diabetes is the primary disease, only a 72 percent survival rate is shown after 1 year; whereas patients with polycystic kidney disease show a 92 percent survival rate for the same period.

Tables 16 and 17 show the patients survival rates after transplantation at 6-month and 1 year intervals. Table 16 shows only Living Related Donor (LRD) transplants, and Table 17 shows only Cadaveric Donor (CAD) transplants. LRD transplant patient survival rates after 1 year are in the 95+ percent range for nearly all categories of patients -- the major exception being those patients age 56 and older. The survival rate after 1 year is 87 percent for this group of patients; this group also has the largest drop in percentage of survival from 6 months to 1 year (95 percent to 87 percent).

Patient survival rates for CAD transplants are slightly lower across all patient characteristic categories than those for LRD transplants. As with LRD, patient survival rates for CAD transplants are lower for the age group 56 and older (from 86 percent at 6 months to 84 percent at 1 year). Primary disease responsible for kidney failure appears to have a bearing on patient survival rates for CAD transplants, although not as significantly as for LRD transplants. Patients with diabetes have the lowest survival rate with regard to primary disease with a CAD transplant: 88 percent at 1 year; while the best survival rate after 1 year is 94 percent for patients with glomerulonephritis. All other categories of primary diseases captured showed a 92 percent survival rate after a 1 year period.

Tables 18 and 19 show the graft survival rates after transplantation at 6-month and 1 year intervals. Table 18 shows only CAD transplants, and Table 19 shows only LRD transplants. Graft survival rates for LRD grafts are very similar for the sexes. After 1 year, the LRD graft survival rate for the white population was 89 percent, while the rate for the black population was appreciably lower at 83 percent. Age had the most dramatic effect on LRD graft survival. Those age 10 and under had only a 75 percent LRD graft survival rate after 1 year. This is in sharp contrast to a 91 percent rate for those age 11-35. After age 35, the survival rates drop slightly, but are still better than for the very young population. There is also a marked difference in LRD graft survival with primary disease. When the primary disease is diabetes the graft survival rate at 1 year is 83 percent. For all other primary disease groups the 1 year graft survival is about 90 percent.

Graft survival rates for CAD transplants overall are much lower than for LRD transplants. CAD graft survival rates range from the low to high 60s, except for two categories. As with LRD grafts, CAD grafts show a lower survival rate for the age group 10 and under; 53 percent at 1 year. Also, those with polycystic kidney disease as their primary disease fare slightly better at 1 year, with a graft survival rate of 71 percent.

TABLE 15 SURVIVAL OF DIALYSIS PATIENTS
(1982 - 1983 Cohort)

<u>Characteristic</u>		<u>N</u>	<u>6 Months</u>	<u>1 Year</u>
Overall		34,025	89 $\pm$.2	81 $\pm$.3
Sex	Male	18,673	89 $\pm$.3	81 $\pm$.4
	Female	15,352	89 $\pm$.3	81 $\pm$.4
Race	Black	9,257	92 $\pm$.3	85 $\pm$.5
	White	23,079	88 $\pm$.2	79 $\pm$.3
	Other	1,347	91 $\pm$.9	84 $\pm$.1
Age	0 - 10	356	95 $\pm$.1	91 $\pm$.2
	10 - 20	1,141	97 $\pm$.6	95 $\pm$.9
	20 - 30	2,957	96 $\pm$.4	92 $\pm$.7
	30 - 40	4,459	94 $\pm$.4	89 $\pm$.7
	40 - 50	4,814	93 $\pm$.4	86 $\pm$.7
	50 - 60	7,574	90 $\pm$.4	83 $\pm$.5
	60 - 70	8,012	86 $\pm$.4	76 $\pm$.6
	70 +	4,689	78 $\pm$.7	65 $\pm$.9
Primary Disease				
	Diabetes	7,340	86 $\pm$.5	72 $\pm$.7
	Hypertension	7,462	89 $\pm$.4	81 $\pm$.6
	Glomerulonephritis	6,894	94 $\pm$.3	88 $\pm$.5
	Polycystic Kidney Disease	1,581	95 $\pm$.6	92 $\pm$.9

(Probability of surviving 6 months or 1 year beyond the first 90 days of chronic dialysis)

TABLE 16 PATIENT SURVIVAL OF LIVING-RELATED RENAL TRANSPLANTS
(1982 - 1983 Cohort)

<u>Characteristic</u>		<u>N</u>	<u>6 Months</u>	<u>1 Year</u>
Overall		2,551	97 $\pm$.3	96 $\pm$.4
Sex	Male	1,584	97 $\pm$.4	96 $\pm$.5
	Female	967	98 $\pm$.5	96 $\pm$.7
Race	Black	297	98 $\pm$.9	95 $\pm$ 1.5
	White	2,165	98 $\pm$.4	97 $\pm$.4
	Other	89	96 $\pm$ 2.3	89 $\pm$ 4.3
Age	0 - 10	116	96 $\pm$ 1.8	96 $\pm$ 1.8
	11 - 35	1,556	98 $\pm$.3	98 $\pm$.4
	36 - 55	775	96 $\pm$.7	94 $\pm$ 1.0
	56+	104	95 $\pm$ 2.2	87 $\pm$ 4.0
Primary Disease				
Diabetes		399	94 $\pm$ 1.2	92 $\pm$ 1.5
Hypertension		199	98 $\pm$ 1.0	95 $\pm$ 1.7
Glomerulonephritis		769	99 $\pm$.4	98 $\pm$.6
Polycystic Kidney Disease		72	97 $\pm$ 2.2	97 $\pm$ 2.2

(Probability of surviving 6 months or 1 year beyond the first 90 days after a LRD transplant)

TABLE 17 PATIENT SURVIVAL OF CADAVERIC KIDNEY TRANSPLANTS

(1982 - 1983 Cohort)

<u>Characteristic</u>		<u>N</u>	<u>6 Months</u>	<u>1 Year</u>
Overall		6,157	93 $\pm$.3	91 $\pm$.4
Sex	Male	3,936	93 $\pm$.4	91 $\pm$.5
	Female	2,221	93 $\pm$.6	92 $\pm$.6
Race	Black	1,425	93 $\pm$.7	92 $\pm$.8
	White	4,493	93 $\pm$.4	91 $\pm$.5
	Other	237	93 $\pm$ 1.7	88 $\pm$ 2.6
Age	0 - 10	92	93 $\pm$ 2.7	93 $\pm$ 2.7
	11 - 35	2,636	95 $\pm$.4	95 $\pm$.5
	36 - 55	2,945	92 $\pm$.5	89 $\pm$.6
	56+	484	86 $\pm$ 1.6	84 $\pm$ 1.8
Primary Disease				
	Diabetes	831	90 $\pm$ 1.1	88 $\pm$ 1.3
	Hypertension	731	94 $\pm$ 1.0	92 $\pm$ 1.1
	Glomerulonephritis	1,623	95 $\pm$.6	94 $\pm$.7
	Polycystic Kidney Disease	358	94 $\pm$ 1.3	92 $\pm$ 1.6

(Probability of surviving 6 months or 1 year beyond the first 90 days after a CAD transplant)

TABLE 18 GRAFT SURVIVAL OF CADAVERIC KIDNEY TRANSPLANTS
(1982 - 1983 Cohort)

<u>Characteristic</u>		<u>N</u>	<u>6 Months</u>	<u>1 Year</u>
Overall		6,157	71 $\pm$.6	66 $\pm$.6
Sex	Male	3,936	71 $\pm$.7	65 $\pm$.8
	Female	2,221	72 $\pm$ 1.0	68 $\pm$ 1.0
Race	Black	1,425	68 $\pm$ 1.3	61 $\pm$ 1.4
	White	4,493	72 $\pm$.7	68 $\pm$.7
	Other	237	69 $\pm$ 3.1	63 $\pm$ 3.4
Age	0 - 10	92	60 $\pm$ 5.3	53 $\pm$ 5.6
	11 - 35	2,636	73 $\pm$.9	68 $\pm$ 1.0
	36 - 55	2,945	71 $\pm$.9	66 $\pm$.9
	56+	484	65 $\pm$ 2.2	60 $\pm$ 2.4
Primary Disease				
Diabetes		831	68 $\pm$ 1.7	63 $\pm$ 1.8
Hypertension		731	71 $\pm$ 1.7	65 $\pm$ 1.9
Glomerulonephritis		1,623	73 $\pm$ 1.1	68 $\pm$ 1.2
Polycystic Kidney Disease		358	76 $\pm$ 2.3	71 $\pm$ 2.5

(Probability of surviving 6 months or 1 year beyond the first 90 days after a CAD transplant)

TAB. E 19 GRAFT SURVIVAL OF LIVING RELATED TRANSPLANTS
 (1982 - 1983 Cohort)

<u>Characteristic</u>		<u>N</u>	<u>6 Months</u>	<u>1 Year</u>
Overall		2,551	91 $\pm$.6	88 $\pm$.7
Sex	Male	1,584	91 $\pm$.7	89 $\pm$.9
	Female	967	90 $\pm$ 1.0	87 $\pm$ 1.2
Race	Black	297	88 $\pm$ 2.0	83 $\pm$ 2.4
	White	2,165	91 $\pm$.6	89 $\pm$.7
	Other	89	91 $\pm$ 3.4	83 $\pm$ 4.9
Age	0 - 10	116	79 $\pm$ 4.0	75 $\pm$ 4.2
	11 - 35	1,556	93 $\pm$.7	91 $\pm$.8
	36 - 55	775	89 $\pm$ 1.2	86 $\pm$ 1.4
	56+	104	90 $\pm$ 3.1	82 $\pm$ 4.2
Primary Disease				
	Diabetes	399	87 $\pm$ 1.8	83 $\pm$ 2.0
	Hypertension	199	93 $\pm$ 2.0	90 $\pm$ 2.2
	Glomerulonephritis	769	93 $\pm$ 1.0	89 $\pm$ 1.2
	Polycystic Kidney Disease	72	88 $\pm$ 4.0	88 $\pm$ 4.0

(Probability of surviving 6 months or 1 year beyond the first 90 days after a LRD transplant)

B. MEDICARE INPATIENT HOSPITAL USE, BY AGE INTERVAL, 1983

Medicare ESRD enrollees received over 1.1 million days of inpatient hospital care during stays for which Medicare made some reimbursement during 1983. This represents an average of almost 2 weeks (13.6 days) of care for each of the 84,000 ESRD enrollees in Medicare as of July 1, 1983. This population, labeled "enrollees at risk" is used as a measure of the ESRD population actually served in some way by Medicare (not necessarily in a hospital setting) and eliminates those enrollees receiving all benefits under other programs (for example, the VA) or erroneously identified as having end-stage renal disease.

The following table displays the number of Medicare "enrollees at risk," the total days of care used, and the number of days per enrollees at risk, by age intervals for calendar 1983.

Table 20

Enrollees at Risk

<u>Aged Interval</u>	<u>Enrollees at Risk</u>	<u>Inpatients Days of Care Used</u>	<u>Days Per Enrollee at Risk</u>
Total	84,013	1,121,245	13.6
0-14	1,334	22,077	16.5
15-24	5,485	63,546	11.6
25-34	12,139	148,780	12.3
35-44	13,230	171,710	13.0
45-54	14,955	193,123	12.9
55-64	18,530	251,788	13.6
65+	18,340	270,221	14.7

Pediatric enrollees, ages 0-14, used the most days of care per enrollees at risk, 16.5 followed by the aged with 14.7 days. Young people aged 15-24 used the least, 11.6.

Several factors affect the variation in inpatient hospital days per enrollees at risk. First is the variation in treatment modalities of the enrollees in each group. The enrollees at risk include persons on dialysis (in-home or in-facility) during 1983, persons transplanted during 1983, and persons transplanted prior to 1983 with the graft still functioning in 1983. For instance, a much higher percent of enrollees age 0-14 are transplanted than in the other age groups. Because transplant patients have high rates of hospitalization, the rates for the age group seem disproportionately high. A second possible cause for the variation by age group is that Medicare covers all inpatient hospital admissions for ESRD enrollees regardless of whether directly ESRD-related or not. Therefore, the age groups will be affected by admissions for reasons other than ESRD.

While not a perfectly accurate indicator of ESRD morbidity, inpatient hospital utilization is a good approximate indicator of the overall health of this population.

C. RATIO OF PATIENTS TRAINED FOR HOME DIALYSIS AND DIALYSIS PATIENTS TRANSPLANTED TO AVERAGE NUMBER OF DIALYSIS PATIENTS

JANUARY 1979 - DECEMBER 1983

	<u>1979</u>	<u>1980</u>	<u>1981</u>	<u>1982</u>	<u>1983</u>
Average Number of Dialysis Patients	40,929	48,879	55,644	62,344	68,876
Patients Completing Home Training	2,874	4,565	5,212	6,282	6,772
Ratio of Home Trained Patients To Average Number of Dialysis Patients	.070	.093	.094	.101	.098
Dialysis Patients Receiving a Tranplant	3451	4051	4268	4772	4528
Ratio of Dialysis Patients Receiving a Transplant to Average Number of Dialysis Patients	.085	.083	.077	.077	.066

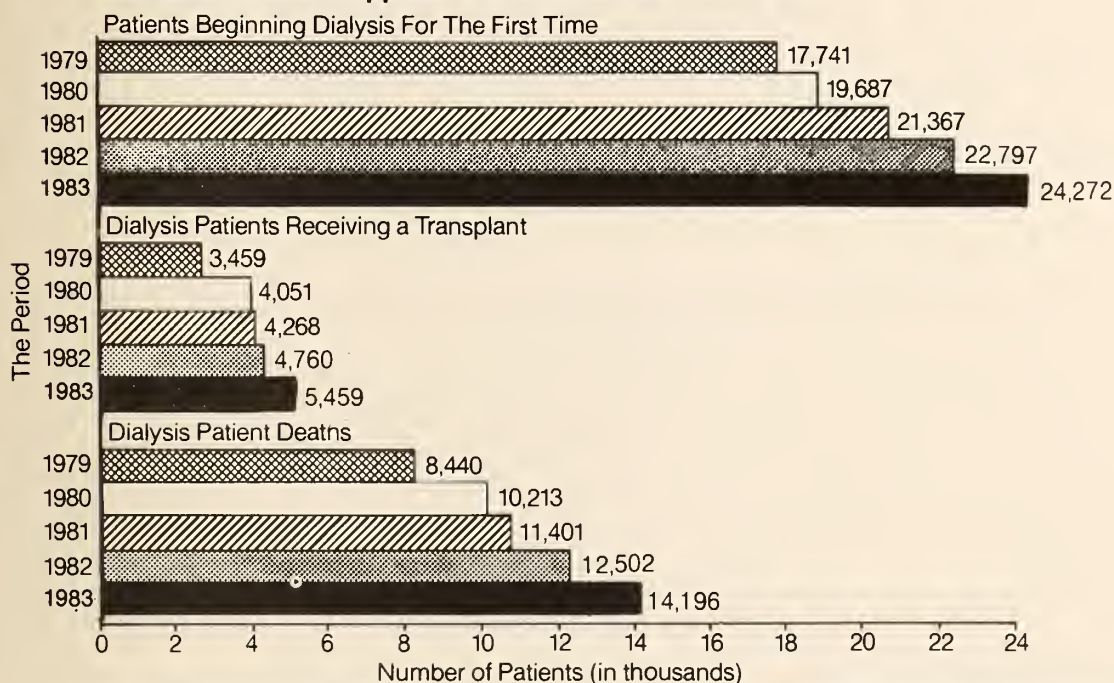
There is an underrepresentation when compared to the number of transplants performed for the years because the survey captures data on the last known status of a patient as of the survey date.

SOURCE: ESRD MEDICAL INFORMATION SYSTEM
1979, 1980, 1981, 1982, and 1983 FACILITY SURVEY

D. MAJOR REASONS FOR CHANGES IN THE NUMBER OF PATIENTS TREATED BY MEDICARE CERTIFIED SUPPLIERS OF ESRD SERVICES 1979-1983

Figure 17

Major Reasons for Changes in the Number of Patients Treated by Medicare Certified Suppliers of ESRD Services 1979-1983



SOURCE: ESRD Medical Information System 1979, 1980, 1981, 1982 and 1983 Facility Surveys

CHAPTER VI

MISCELLANEOUS

A. COST SAVINGS AND OTHER ESRD EXPERIMENTS

The Office of Research and Demonstrations within the Health Care Financing Administration (HCFA) is currently funding several studies related to the End-Stage Renal Disease (ESRD) Program. Two of these studies described in this report correspond to specific mandates in Public Law 95-292. The remaining 11 studies are classified as Department/Agency initiatives. These projects address many of the basic policy, program evaluation, and cost containment issues involved in administering the ESRD program.

A list of research and demonstration studies which are described in the following pages, and which are in various stages of completion, includes:

MANDATED STUDIES

1. A study of incentive systems and the donation of cadaver kidneys.
2. A study of physicians who care for ESRD patients - their practices, patients, and patient care.

HHS/HCFA INITIATED STUDIES

1. A study of the quality of life, quality of care, cost of care and rehabilitation of ESRD patients under different treatment modalities.
2. A study of costs, outcomes, and competition in the ESRD program.
3. An epidemiological study of the relative risks of chronic low level exposure to solvents and heavy metals and the incidence of ESRD.
4. An organ donor education project.
5. A demonstration of the feasibility of using competitive approaches for the reimbursement of ESRD services.
6. A study of the cost and effectiveness of treatment modalities for ESRD patients.
7. A laboratory test of the feasibility of developing a wrist wearable hemodialysis machine.
8. A comparative analysis of the costs and outcomes of kidney transplantation.
9. A study of the impact of DRG's on the ESRD population.
10. A study of case severity in the ESRD population and its relationship to resource consumption.
11. A study comparing the quality of life of ESRD patients.
12. A study of the clinical and cost effectiveness of nutritional therapy in the prevention or delay of renal failure.

MANDATED STUDIES

1. In June, 1983 HCFA awarded a grant to the Brandeis University entitled, "Developing Incentive Systems to Increase the Supply of Cadaveric Kidneys for Transplants."

Using survey methodologies, this project will evaluate alternative approaches to increasing the participation of nongovernmental actors in organ procurement programs. The end result of the research will be a set of Health Care Financing Administration policy recommendations designed to improve the effectiveness of organ procurement networks and so increase the number of kidneys available for transplantation.

The grant was initiated in June of 1983. Currently, the project is in the data collection phase.

2. In March 1982 HCFA awarded a grant to the University of Southern California entitled, "Physicians Who Care for End-Stage Renal Disease Patients: A National Study of Their Practices, Patients and Patient Care."

The researchers proposed to design and conduct a national physician oriented study of the time and effort allocated to various professional activities and patient care services with the target population being those physicians who render care to patients with ESRD. The study is all-inclusive to the extent that the participating physicians are asked to report on their entire practice and the full array of their professional activities. The physician population was limited to those who were reimbursed under the alternative method and the sample was selected from those physicians who are linked administratively and operationally for some patient care with one or more dialysis facilities - making it possible to draw statistically valid conclusions about the actual care provided to both ESRD and non-ESRD patients, and with the ESRD patient services explicitly linked to a particular type of dialysis facility and dialysis modality.

Using a log diary approach, detailed information was obtained on specific services rendered to ESRD beneficiaries by 327 physicians. The final study report, received in February 1984, includes both a descriptive analysis of the data, identifying patterns evident in the data by region, facility workload, and case-mix as well as an examination of the complex facility characteristics, and variations in treatment. Data from the survey show that ESRD Physicians' workloads parallel the busy practices of generalist physicians more than they do the practice patterns of most subspecialists in medicine (except that the outpatient load occurs mainly in the dialysis unit). Patient encounter data show that the majority of their visits are with ESRD patients, and that over half of all ESRD patients (facility and self care combined) are seen once a week or more. ESRD physicians report seeing facility hemodialysis patients an average of between 1.6 and 1.7 times a week. The telephone is used primarily for communicating with other health professionals, and calls with patients are primarily with non-ESRD patients. There are pronounced differences in the morbidity profiles of patients on different types of dialysis; home hemodialysis patients were found to have low rates of serious systemic illnesses, whereas peritoneal dialysis patients have high rates of diabetes mellitus. IPD patients are the sickest patients on a number of criteria, but there is little evidence to indicate that patients treated in hospital-based hemodialysis centers are any

sicker than those in freestanding facilities. Finally, physicians with the highest workloads provide less resource intensive care (less time spent with the patient and fewer diagnostic tests employed) even when medical complications and other sources of variation in care are controlled for statistically.

HHS/HCFA INITIATED STUDIES

1. A STUDY OF ALTERNATIVE TYPES OF THERAPY FOR ESRD PATIENTS

HCFA awarded a grant, "The Impact of Alternative Types of Therapy on Patients with End-Stage Renal Disease," to Battelle Memorial Institute's Human Affairs Research Center in January 1981. The study focuses on several variables of interest to the program including an examination of quality of life, quality of care and cost of care to patients undergoing different types of therapy for treatment of ESRD. The study also examines the extent of disability among dialysis patients and assesses the potential for improving the lives of dialysis patients by changes in the types of therapy or through the provision of rehabilitation services. Four treatment modalities are included in the study: facility dialysis, home dialysis, continuous ambulatory peritoneal dialysis (CAPD) and renal transplantation.

During the first year of the study, the researchers developed a detailed study protocol and obtained participating agreements and institutional review board clearances. A two-stage sampling design based on a stratified probability sample of ESRD patients by treatment modality from 11 facilities and transplant centers was developed and a study universe of 950 renal patients was drawn. Several different survey instruments were developed and pretested. The primary data collection instrument, the patient interview schedule, was administered to the study population. Other instruments included a patient health, medical care, and treatment expenses diary and a chronic renal disease patient medical records data abstraction form.

During the second year of the study, the major activities included the completion of the data collection activities, the preparation of the data tapes, the initial data runs, including descriptive, univariate and selected cross tabulation, simple chi-square tests of differences, analysis of variance and covariance, multiple regression analyses, and the publication of several supporting documents and papers. For analytical purposes, the data are grouped into nine data clusters corresponding to the following type of variables: sociodemographics, health status, functional impairment, work disability, type of therapy, social environment, quality of care, and cost of care. Several standard measurements and indexes were utilized in the study to permit cross-validation with other research studies. The third year of the study was devoted to the analysis of the data and preparation of several additional reports. A comprehensive monograph on the study and its findings will be published by HCFA under its Special Reports series during FY 1985.

The major papers which have been published from the study and their abstracts are as follows:

- (1) Case-Mix, Treatment Modalities, and Patient Outcomes: Results of the National Kidney Dialysis and Kidney Transplanatation Study.

"Many studies which have examined the outcomes of patients with end-stage renal disease have attributed differences in observed outcomes to treatment modality. It is unclear, however, whether these differences are truly due to treatment modality or whether they

are a result of initial patient selection differences, more appropriately described as case-mix differences. In this paper data are analyzed for 859 patients from 11 different dialysis and transplantation centers who are on four different treatment modalities - home hemodialysis, in-center hemodialysis, continuous ambulatory peritoneal dialysis, and transplantation. It is found that substantial case-mix differences exist among patients on these four major treatment modalities. With regard to outcomes, it is found that patients on kidney transplantation and home hemodialysis are more likely to be working and have a lower level of functional impairment than patients on the other modalities. The analyses also show that while case-mix can be an important determinant of outcomes, a modality effect persisted once sociodemographic and medical case-mix factors were statistically controlled. Finally, a direct comparison of patients across centers suggests that, in addition to a case-mix and a modality effect, there appears to be a unique center effect which accounts for differences in patient outcomes. Based on results presented here, it is suggested that future studies which relate treatment modalities to patient outcomes must take into consideration the fact that any relationship between the two may be the result of one or more of the following effects --case-mix, modality, or center."

(2) A Comparative Assessment of the Quality of Life of Patients Undergoing Treatment for Chronic Renal Failure.

"The quality of life of 859 patients from 11 dialysis and transplantation centers across the United States was assessed. All patients were on one of four treatment modalities--home hemodialysis, in-center hemodialysis, continuous ambulatory peritoneal dialysis, and transplantation. The results show that the relationship between treatment modality and seventeen subjective indicators of quality of life (i.e., life satisfaction, general well-being, and happiness) remain relatively unchanged once patient case-mix factors have been controlled. Case-mix factors subjected to analyses include age, sex, race, education, and comorbidity. These results suggest that once patient case-mix has been controlled, treatment modality still independently affects patients' assessment of quality of life. Based on these results, it is possible to rank treatment modalities according to the quality of life associated with them. Transplant patients consistently report a higher quality of life than patients on other treatment modalities, although home hemodialysis patients are similar in many respects. CAPD patients appear to have a higher quality of life than failed transplant patients, while in-center hemodialysis patients are clearly the worst off. Finally, quality of life comparisons between ESRD patients and the general population reveal that the life circumstances of ESRD patients are not as poor as previously envisioned."

(3) Functional Impairment, Work Disability, and the Availability and Use of Rehabilitation Services by Patients with Chronic Renal Failure.

"Recently, there has been an increased awareness of and concern about the rehabilitation of patients with end-stage renal disease (ESRD). Little is currently known about the work disability, functional

impairment, and use of rehabilitation services by ESRD patients. In this paper data are analyzed for 859 patients from 11 dialysis and transplantation centers who are on four different treatment modalities--home hemodialysis, in-center hemodialysis, continuous ambulatory peritoneal dialysis, and transplantation. Results presented here reveal that transplant patients experience the least functional impairment, followed by home hemodialysis patients, failed transplant patients, in-center hemodialysis patients, and CAPD patients. Ignoring distinctions among patients on different treatment modalities, approximately 32.0 percent of the patients in this study were unable to carry on normal activity. The remainder of the patients were either unimpaired or only minimally impaired. Work disability among patients also varied according to treatment modality with transplant patients most likely to be working. Overall, 30.0 percent of the patients were working either full-time or part-time. Approximately 39.0 percent of the patients said they were disabled. Finally, only 54.6 percent of the patients made use of available rehabilitation services. Transplant patients, both those with failed and functioning grafts, used more rehabilitation services than the other patient groups. Based on these results, it would appear that a larger number of patients could potentially benefit from the use of rehabilitation services. For unspecified reasons patients are unaware of services which are available to them, choose not to use the services, or are denied access to the available services."

(4) Labor Force Participation Among ESRD Patients.

"Recently, there has been an increased concern about the rehabilitation of patients with end-stage renal disease (ESRD). In particular, interest has focused on their participation in the labor force. In this paper results are presented based on the analysis of data obtained from 859 patients associated with 11 dialysis and transplantation centers in the U.S. The patients are on four different treatment modalities including home hemodialysis, in-center hemodialysis, continuous ambulatory peritoneal dialysis (CAPD), and transplantation. When adjusted for patient case-mix, the data show significant differences in the labor force participation among patients on all four treatment modalities. More specifically, transplant patients are more likely to be working followed by patients on home hemodialysis, in-center hemodialysis, and CAPD. Once patient case-mix (i.e., age, gender, race, education, wealth, and health) is statistically controlled, however, several of these differences are greatly reduced. It is noteworthy that despite case-mix differences, transplant patients continue to have the greatest likelihood of participating in the labor force and that CAPD patients are the least likely. Home hemodialysis patients, when compared with patients on all other treatment modalities, are only slightly more likely to be working than their in-center counterparts. A more detailed multivariate analysis, however, reveals that white, male, home hemodialysis patients between the ages of 25 and 59 are significantly more likely to be working than in-center patients of these characteristics. This finding does not hold, however, for either females, or nonwhite males in this age range. It is concluded that these findings have important implications for public policy but must

be carefully evaluated in light of acknowledged limitations in both the data and the analyses."

(5) Health Services Utilization and Disability Days: Indicators of the Quality of Patient Care Among ESRD Patients.

"This report focuses on several outcome measures as indicators of the quality of care of end-stage renal disease (ESRD) patients. Variables reflecting hospital utilization, disability days and physician visits were compared for five different treatment modality groups. With respect to hospital utilization, statistically significant differences were observed across treatment modalities. In addition, a relationship was observed between the utilization of hospital services and length of time on current treatment modality. Statistically significant differences in hospital utilization were observed across treatment modalities among patients who had been on their current treatment modality for one year or less. However, among patients who had been on their current treatment modality for more than one year, statistically significant differences across treatment modalities were not observed.

Differences in outcome variables were then examined, controlling for the sociodemographic (age, sex, race, education) and medical characteristics (diabetes, comorbidity, length of time on current modality) of the patient groups. Medical factors, in particular comorbidity and length of time on modality, were more important than the sociodemographic factors in explaining the observed variation in health services utilization across modalities. Treatment modality, however, remained a significant variable in the case of five of the seven utilization variables."

(6) Premorbid and Post-Treatment Functional Limitations Among Patients with Chronic Renal Failure.

"This report focuses on the functional limitations of patients undergoing treatment for end-stage renal disease (ESRD). Results presented here clearly show that ESRD patients are more impaired at the present time than they were prior to the onset of kidney disease. Overall, patients in this study did not differ, regardless of their current treatment modality, in their level of functional impairment prior to the onset of kidney disease. But, at the present time significant differences across patients on different treatment modalities are found. Both transplant and home hemodialysis patients are found to be less debilitated than in-center hemodialysis patients, CAPD patients, and patients who have experienced a failed kidney transplant. Indices of both general and specific functional impairment are consistent in this regard. Several explanations are offered for the association between treatment modality and functional impairment, including the possibility that patient case-mix may account for the observed differences. The study results also suggest that patients could potentially benefit from more aggressive physical rehabilitation efforts. Only 16 percent of the patients in the study had ever made use of physical therapy. Finally, the need for a longitudinal study of ESRD patients is indicated."

(7) The Use of Rehabilitation Services By Patients with Chronic Renal Failure: Results from the National Kidney Dialysis and Kidney Transplantation Study

"The use of rehabilitation services by 859 patients randomly selected from 11 dialysis and transplant centers across the United States was assessed. All patients were on one of four treatment modalities--home dialysis (CAPD), and transplantation. In addition, dialysis patients who previously had a failed kidney transplant were analyzed separately. The results show that while most dialysis and transplant centers participating in the study offered a full array of rehabilitation services, only 53.5% used more than one service. Use of services varied significantly across treatment modalities, with failed transplant, patients reporting the highest utilization, followed by successful transplant. Among patients who had used one or more services, 24.5% had services arranged for them by the hospital and 13.3% by the kidney center. Another 22.7% indicated that their doctor had helped arrange for services, while 16.7% indicated that a social worker was involved. Based on the results of other studies, it is concluded that ESRD patients are not likely to have met their true rehabilitation potential."

(8) Peritonitis, Hospital Admissions, and Days Hospitalized Among Patients on Continuous Ambulatory Peritoneal Dialysis (CAPD) and Continuous Cycling Peritoneal Dialysis (CCPD): A Comparative Assessment

"Sixty-one continuous ambulatory peritoneal dialysis (CAPD) patients and twenty continuous cycling peritoneal dialysis (CCPD) patients were compared with respect to incidence of peritonitis, hospital admissions, and days-hospitalized. CCPD patients were found to have a lower incidence of peritonitis, fewer hospital admissions, and fewer days hospitalized than CAPD patients. These differences are not markedly influenced by patient case-mix factors, since the two patient groups differ only with respect to age. CAPD patients, on average, are older than CCPD patients. It is argued that the differences in morbidity and use of hospital services are largely due to differences in dialysis technique. It is concluded that among patients for whom peritoneal dialysis is most appropriate, CCPD represents an increasingly attractive alternative to CAPD and intermittent peritoneal dialysis (IPD). Not only does CCPD retain many of the advantages of CAPD, but it does not impose upon the patient the numerous disadvantages of CAPD and IPD."

(9) Extrarenal Complications among Kidney Transplant Recipients

"Both short - and long - term complications are associated with organ transplantation. Prevalence of complications is assessed among 144 patients with functioning renal allografts and 116 patients with failed allografts who are back on renal dialysis. Data are presented which

show that serious complications, other than cancer, such as cardiovascular problems other than angina and myocardial infarction, gastrointestinal problems, neurological disorders, and musculoskeletal disorders are more likely to be present among end-stage renal disease patients who have experienced a failed kidney transplant than among those patients who have successfully functioning allografts. These differences are not attributable to patient case-mix differences since the two patient groups do not differ with regard to age, sex, race, education, and primary disease diagnosis."

(10) Travel Cost and End-Stage Renal Disease

"Travel costs, involving both time and transportation expenditures, are important social costs associated with the treatment of end-stage renal disease (ESRD). In this paper data are analyzed on travel costs incurred by 859 patients on four different ESRD treatment modalities. In-center hemodialysis patients, although living closer on average to their treatment center than those on other modalities, are found to incur substantially greater travel costs than those on other modalities. On average, they spend 110 hours per year travelling approximately 2500 miles. Valuing these in dollars yields costs to society of travel by in-center patients on the order of \$1500 - \$2000 per patient per year. Home hemodialysis patients generated the lowest travel costs on average."

(11) End-Stage Renal Disease patient Preferences for Dialysis and Transplantation

"Eight hundred and fifty-nine end-stage renal disease (ESRD) patients at 11 dialysis and transplant centers across the U.S. were surveyed concerning their preferences for various ESRD treatment modalities. Patients were currently on home hemodialysis, in-center hemodialysis, continuous ambulatory or continuous cycling peritoneal dialysis (CAPD and CCPD), or had a functioning kidney transplant. The majority of patients preferred their current treatment, although transplantation was the most popular modality overall. Many patients had considerable modality experience, for example, transplant and CAPD patients had each been on an average of 2.3 modalities. In-center hemodialysis patients had the least modality experience (1.3 modalities). Patients who had experienced both in-center and home hemodialysis differed in their perceptions of these modalities. Patients who had a previous failed graft and were retransplanted preferred transplantation to any other modality. In-center hemodialysis was the least preferred modality among all patient groups. While neither sex nor race distinguished patient preferences, younger patients preferred transplantation."

(12) A Comparative Assessment of the Quality of Life of Successful Kidney Transplant Patients According to Source of Graft

"Survival rates, graft retention rates, and patient rehabilitation among kidney transplant recipients have all been differentiated on the basis of graft source. Generally, patients with cadaveric grafts have lower survival rates, lower graft retention rates, and poorer rehabilitation profiles than do the recipients of living related donor grafts. Results presented here based on an analysis of 144 renal transplant recipients at six transplant centers, however, show that neither objective nor subjective quality of life among successful renal transplant recipients is affected significantly by source of graft or patient case-mix factors including age, sex, race, education, primary disease diagnosis, comorbidity, or length of time with current transplant. Thus, while a patient undergoing a cadaveric transplant may incur somewhat greater risks than the recipients of living related donor grafts, if the transplant is successful, their quality of life is not unlike that of living related graft recipients."

(13) Income and Poverty Among End-Stage Renal Disease Patients: Results from the National Kidney Dialysis and Kidney Transplantation Study

"This paper describes the income distribution and prevalence of poverty among a sample of ESRD patients. The data were collected from a survey of 859 patients in the National Kidney Dialysis and Kidney Transplantation Study. The incomes of patients on four modalities are compared with the general U.S. population. The prevalence of poverty among the families of ESRD patients is estimated, and the impact of federal income support in alleviating poverty is determined. The results show that ESRD patients' families are poor relative to all U.S. households, and are indeed poorer than would be expected on the basis of the age and racial composition of the ESRD population. Nearly two-thirds of the ESRD population are receiving federal income support, and yet nearly 30 percent of ESRD patients are living in households below the poverty line."

2. COST OUTCOMES AND COMPETITION IN THE ESRD PROGRAM

In June 1981, HCFA awarded a grant to the Urban Institute to examine the variations in costs and treatment outcomes to identify those factors associated with lower cost and/or higher survival rates.

Factors to be considered include case-mix, facility size, and physician compensation methods. In addition, a specific focus of the project will be an examination of the effects of competition between ESRD facilities. The project will assess whether free entry into the dialysis market either reduces costs or provides increased benefits to patients. A survey will be conducted to identify facility initiatives to attract and retain patients where several facilities are available to beneficiaries. Finally, the study will also examine the cost impacts of the certificate of need and minimum utilization rate requirements.

The study is primarily based on an analysis of the ESRD MIS data base (facility survey, cost survey, nonreimbursement patient records and billing records) and supplemented by a telephone survey of 700 facility medical directors (300 independent and 400 hospital-based facilities).

The most important policy areas to be covered in the study are:

(a) Provider Reimbursement

- o Should facility and/or physician reimbursement be based on capitated payment per patient with such payment covering all costs including hospital charges?
- o Should case mix adjustment be an element of reimbursement?
- o What elements of costs are directly related to facility size and how should reimbursement be designed to encourage optimal size?
- o Does ownership and facility type affect total cost in ways not attributable to case mix?

(b) Physician Compensation

- o What is the relationship between physician compensation method and total cost per patient?
- o Does the present physician capitation method need modification to provide better cost-saving incentives?
- o Are there different health outcomes under the two methods?
- o Should one method be emphasized over the other?

(c) Competitive Effects

- o Does restriction of the number of stations through minimum utilization rates and certificate of need actually help to control costs?

- o Would free entry into the dialysis market either reduce costs or provide increased benefits to patients?

(d) Ownership Status

- o Are there measurable differences in the health outcomes of patients treated at for-profit facilities?
- o Should entry by investor-owned firms be encouraged or discouraged?

(e) Self-Care Patients

What are the savings in self-care when case mix adjustments have been included in the analysis? Do these savings warrant continued emphasis on self-care?

(f) Home Dialysis

- o What contributions to a center's operating costs are made by home patients?
- o When total costs, including all hospital care are considered, how much savings result from home care?

Four reports have been published to date. In the first report: "Pro-Competitive Health Insurance Proposals and Their Implications for Medicare's End-Stage Renal Disease Program," published in Seminars in Nephrology (August 1982), the authors discuss several ways of inducing competitive behavior into the ESRD program, although significant implementation problems would exist that would require careful attention to both cost and quality-access incentives.

In the second report, "Competition and Efficiency in the End-Stage Renal Disease Program," published in Journal of Health Economics (August 1983), the authors argue that although analyses of costs and productivity are useful, they are not conclusive in determining reimbursement levels. The problem is that reimbursement levels and competition among providers determine the level of amenities offered and these in turn influence the costs rather than the converse. The thesis is thus that the determination of the reimbursement level requires a prior political decision on the level of amenities such as conveniences, access, and medical quality the taxpayers will finance.

The focus on the report is on the impact of the presence or absence of competition. A simple model is presented to show that the level of amenity can be affected by the level of reimbursement and the level of competition. Then the argument is developed that this amenity bias can affect estimates of costs, cost functions, and production functions. Next, the authors present empirical evidence to show that this is more than

theoretical speculation. With output price approximately fixed, they found that profits from dialysis services are indeed affected by the degree of competition. Competition is also shown to be positively related to an observable measure of the level of amenity. Finally, the implications of this competition-amenity interaction on estimating and interpreting a production function for this type of health care are illustrated. The authors indicate that such estimates are subject to a previously unrecognized "unobserved amenity bias."

In the third report, "Continuous Ambulatory Peritoneal Dialysis: Preliminary Evidence in the Debate Over Efficacy and Cost," published in Health Affairs (Summer 1983), four preliminary conclusions are reached: (1) The routine information collected by Medicare on patients with renal failure offers a potential source of useful information for policy analysis; (2) The new dialysis patients (1981) using Continuous Ambulatory Peritoneal Dialysis (CAPD) appeared to be "sicker" at the time of entry into therapy than patients using facility hemodialysis based on the data and criteria developed in this paper; (3) Regardless of initial diagnoses and other readily measured patient characteristics such as age, sex, race, the data reported here do not suggest a higher death rate for CAPD patients in the first year of therapy; and (4) CAPD patients, controlling for demographics and initial diagnosis appear to have a substantially higher rate of hospital usage than do hemodialysis patients.

In the fourth report, "Charging the Victim: An Evaluation of Reimbursement Policy in the End Stage Renal Disease Program," published in E. Helpman, et al, Social Policy Evaluation: An Economic Perspective (Academic Books, New York, 1983), the evaluation rests on two bases. On the one hand, an empirical investigation of facility production functions indicated the way productivity varied with a number of characteristics of reimbursement systems and facilities, and an empirical investigation of the determinants of amenity showed that amenity did vary with competition and facility ownership. On the other hand, simple economic theory could be combined with these results to evaluate the desirability of various schemes.

While the potential impacts of various devices of a reimbursement behavior were evaluated, the authors were unable to move from such positive analysis to a normative prescription of an "ideal" reimbursement rate. This is because literally any fixed rate is conducive to cost minimization (at least for the predominant for-profit firms), but the level of the rate determines the level of amenity and accessibility (depending on the degree of competition and profit.) Without an explicit statement about (or even definition of) the ideal level of these characteristics, it is not possible to fix a reimbursement rate. Analysis is, nevertheless, useful to pointing out that there are likely to be conflicts between regulators interested in reducing program costs and renal disease patients interested in making their lives as bearable as possible.

This grant is scheduled to expire in May 1984.

3. AN EPIDEMIOLOGICAL CASE-CONTROL STUDY TO DETERMINE THE RELATIVE RISKS OF CHRONIC LEVEL EXPOSURE TO SOLVENTS AND HEAVY METALS AND THE INCIDENCE OF END-STAGE DISEASE.

HCFA is collaborating with the National Institute of Occupational Safety and Health in a case-control study to investigate if long-term exposure to industrial solvents, silica and heavy metals might be associated with the incidence of ESRD. Heavy exposures to many of these industrial products are known to increase the probability of kidney disease, but the effects of low level exposures are not known.

In this study, approximately 400 cases and an equal number of controls will be interviewed and questioned on the type and extent of exposure to these expected risk factors. The study is a community based study of males between the ages of 19 and 50 who live in the Detroit SMSA area and who have worked in the industrial plants.

The study began in the summer of 1983 and will conclude by December 1985.

4. ORGAN DONOR EDUCATION PROJECT

A grant was awarded in May 1983 to the Oregon Donor Program to test a public education method for promoting donations of all retrievable organs. The objective of the 1-year project is to increase the number of potential donors, i.e. driver's licenses coded for organ donation, through showing video tapes on this subject in Oregon Department of Motor Vehicles (DMV) Offices. Two video tapes would be utilized: a 2-minute public education tape to be shown to driver's license applicants, and an 8-minute tape to be shown to DMV personnel to train them to promote organ donation. In addition, an information manual about organ donation procedures will be developed and distributed to medical personnel, chaplains, and others who influence potential donors and their next of kin.

The evaluation of the video tapes will compare the number of donor licenses received from three groups of randomly assigned DMV offices: (1) those in which both the personnel and the public tapes were shown; (2) those in which only the personnel tape was shown; and (3) those in which no tape was shown. Similarly, the organ donation manual will be evaluated by comparing the number of donors at hospitals from two groups of stratified and randomly assigned hospitals: one group in which the manual was utilized, and a control group in which it was not utilized. The demonstration is scheduled to begin in Spring 1984.

5. COMPETITIVE APPROACHES TO ESRD REIMBURSEMENT

In March 1983, HCFA awarded a grant to the Urban Institute to determine the feasibility of testing various competitive approaches to reimbursing ESRD services. The approaches to be considered include competitive bidding, partial capitation covering only outpatient services, global capitation covering essentially all medical care costs, and voucher systems allowing patients to share in the savings of cost-reducing shifts of services.

The 2-year study will explore whether savings will result when providers and/or patients share in both the costs and benefits of their decisions on how much, and what type of services to use, and the impact on quality of care and access.

If the study establishes that one or more of such approaches are feasible, Urban will develop demonstration models and designs for their evaluation. These models will include consideration of appropriate capitation or voucher amounts, reinsurance systems, and relations to other payers. Urban has completed a design for the assessment of HCFA's Competitive Bidding Demonstration (see below). Urban's next report will consider issues relating to other competitive bidding models. It will (1) cover the characteristics of competitive bidding, in general, and its implications for ESRD and other services, and (2) cover how bidding could apply to the ESRD program, including the pros and cons of particular approaches.

HCFA Competitive Bidding Demonstration

HCFA is preparing to implement a demonstration to test the differences of one competitive bidding approach, as an alternative reimbursement method for ESRD outpatient dialysis services. Under this 3-year study, each dialysis unit in two selected sites will be requested to submit a bid (updated after 6 months) for the price at which it will deliver services to Medicare patients. Medicare reimbursement to the unit will be based on the rate established by the bid rather than the unit's regular composite rate.

The demonstration will include a beneficiary incentive, whereby beneficiaries will be eligible to receive an incentive payment equal to 70% of the difference between the composite rate for freestanding units and the bid price. The Medicare program would retain the remaining 30% share of the savings. While the intent is to encourage beneficiaries to utilize lower price units, beneficiaries will be free to select any unit, and no unit will be excluded from participation in the Medicare program. In choosing where to dialyze, patients will thus be motivated to seek the best combination of low price and high quality, convenience, and other valued factors. Units will be motivated to bid below the standard payment where they can thereby benefit from attracting (or retaining) more patients.

The Urban Institute has prepared an evaluation plan for the demonstration and will collect baseline data to be used in the evaluation. The evaluation plan provides for determining whether the demonstration produced cost-effective changes in beneficiary and provider behavior, and impacts on quality, case-mix, and style of care. An independent contractor will be selected to perform the evaluation.

The demonstration is scheduled to begin in Spring 1984.

6. A STUDY OF THE COST AND EFFECTIVENESS OF TREATMENT MODALITIES FOR ESRD PATIENTS

A grant was awarded to the University of Michigan, Department of Epidemiology, in September of 1983 to conduct a 5-year study called, "Relative Effectiveness and Cost of Transplantation and Dialysis in End Stage Renal Disease." This project will empanel a cohort of patients entering the Michigan Kidney Registry for the first time in 1980/81 and another panel of patients entering in 1984. The study will collect point and period prevalence and incidence data by direct and indirect follow-up patients over two 2-year intervals to:

- (a) characterize the treatment modalities of the patients;
- (b) quantify the differences between the two main modalities of care and their subgroups in terms of effectiveness;
- (c) measure differences on survival of patients;
- (d) measure the impact of the use of cyclosporine on effectiveness and costs of care;
- (e) measure the effect of the introduction of continuous ambulatory peritoneal dialysis on the effectiveness and costs of all the treatment modalities; and
- (f) develop a database model for a health intelligence system suitable for use by various agencies for making policy and program decisions on issues relating to the provision of services for ESRD patients.

7. In September 1983, HCFA awarded a grant to Vitor, Inc. entitled, "Inexpensive Wrist-Wearable Artificial Kidney for 24-hours-a-day, 7-days-a-week hemodialysis.:

This was a small business innovation research project. The intent of the study was to begin the design and testing of a miniature artificial kidney which could be worn on the wrist like a bracelet. This machine could be worn for as long as 1 week. It would use small replaceable dialyzer cartridges. The testing phase involved measuring the efficiency of the wrist dialyzer against the larger dialysis machines in a laboratory setting.

The project was completed in March 1984. The grant results were sufficiently favorable to justify submission of a larger grant proposal to the National Institutes of Health.

8. In July 1984, HCFA awarded a cooperative agreement to the Battelle Human Affairs Research Centers entitled, "A comparative analysis of the cost and outcomes of kidney transplantation."

The researchers propose to study the costs and implications of cyclosporine. The objectives are as follow:

To determine whether the case-mix of patients transplanted under cyclosporine protocols differs from those on conventional therapy.

To analyze the comparative cost-effectiveness of immunosuppressive treatment regimens including the conventional protocol (azathioprine and prednisone) and the most recent protocol (cyclosporine and prednisone).

To examine the diffusion of cyclosporine among renal transplant teams in the U.S.

This study is to be carried out in a number of transplant centers on about 300 patients transplanted between January 1985 and December 1986. Patients are to be followed for up to 2 years depending on when they enter the sample. Detailed medical and financial information will be collected on all patients. Outcome measures include graft and patient survival, costs of therapy, morbidity, functional status, employment status, and quality of life indicators.

9. In July 1984, HCFA awarded a cooperative agreement to the Urban Institute entitled, "Learning from and Improving DRGs for ESRD Patients."

The objective of this study is to evaluate the impact of prospective payment on ESRD patients by testing for unintended consequences such as DRG "creep," cost shifting, and underservice of "bad risk" high cost patients. The research questions are as follows:

- (1) How does the current DRG system treat ESRD patients' hospital cases?
- (2) How manipulatable are DRGs as they apply to ESRD patients?
- (3) In practice, how have PPS/DRGs worked and what are the system's impacts along a whole variety of dimensions?

Changes in admission rates for ESRD patients will be examined with emphases on variations: (a) by type of provider; and (b) by type of patient. The analyses will also be sensitive to changes in DRG use that may indicate a shifting of patients from the outpatient setting to inpatient care for routine dialysis.

10. In September 1984, HCFA awarded a cooperative agreement to the University of Florida entitled, "Severity of Illness in the End-Stage Renal Population in Northern Florida."

This project has the following objectives:

- (a) To develop measures of severity in the ESRD patient population that predict resource consumption and therefore can be used to refine reimbursement methods;
- (b) To determine whether the mix of patients in hospital facilities is more severe and requires more intense services than the mix found in freestanding facilities;

- (c) To determine how utilization of dialysis and nondialysis resources relate to patient severity of illness.

The major part of the study will entail the development of monthly measures of treatment intensity and physiological derangement on a sample of approximately 300 dialysis patients.

- 11. In September 1984, HCFA awarded a cooperative agreement to the University of Minnesota entitled, "Comparison of the quality of life of End-Stage Renal Disease patients."

This study is designed to contrast various quality of life measures for five groups of ESRD patients:

- (1) patients transplanted between 1970 and 1973 (historical comparison group);
- (2) current center hemodialysis patients;
- (3) current CAPD patients;
- (4) current transplanted patients - conventional immunosuppression therapy;
- (5) current transplant patients - cyclosporine.

Patients from the different treatment modalities were selected in different ways. Transplant recipients were selected from patients who are part of a larger University of Minnesota project grant. Center hemodialysis patients were selected from eight local dialysis centers. CAPD patients were selected from the National CAPD registry maintained by the National Institutes of Health. Three dimensions of quality of life are specified; physical, social, and emotional. Measures of these dimensions were taken from extant psychological scales and are comparable to other studies in this area.

12. END-STAGE RENAL DISEASE NUTRITIONAL THERAPY STUDY

Description: In accordance with the Congressional mandate (Public Law 96-499), this study will seek to determine (1) the extent to which the commencement of nutritional therapy in early renal failure (utilizing controlled protein substances) can retard or arrest the progression of the disease with the resultant substantive deferment of dialysis, and (2) the administrative, financial, and other aspects of making nutritional therapy generally available under Medicare. The study will be conducted jointly by the National Institutes of Health (NIH) and the Health Care Financing Administration. Initiation of full-scale clinical trials will be preceded by a developmental phase and a pilot test.

Status: The development phase began in September 1984. The NIH has awarded six clinical centers to conduct the clinical trials and the preliminary phases. The data coordinating center has been awarded. The clinical centers are:

Division of Nephrology and Hypertension
Harbor-University of California at Los Angeles
Medical Center
1000 W. Carson Street
Torrance, Calif. 90509

Veterans Administration Medical Center
Building 3
Iowa City, Iowa 52240

Department of Pharmacology and Experimental Therapeutics
Johns Hopkins University
725 N. Wolfe Street
Baltimore, Md. 21205

New England Medical Center
Box 784
171 Harrison Avenue
Boston, Mass. 02111

Renal Division
Brigham and Women's Hospital
75 Francis Street
Boston, Mass. 02115

Vanderbilt University Medical Center
Division of Nephrology
Room B-2214 MCN
Nashville, Tenn. 37232

B. RESULTS OF BASIC KIDNEY DISEASE RESEARCH

A. General Description

The National Institutes of Health/National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases supports research within a broad area related to chronic renal disease. There are three main subdivisions of the Chronic Renal Disease program: pathophysiology of chronic renal failure, renal transplantation, and maintenance therapies for end-stage renal disease.

Principal Research Areas of the Chronic Renal Disease Program

1. Pathophysiology of Chronic Renal Failure.

These projects are devoted to the investigation of systemic abnormalities of uremia such as bone disease, anemia, and neurological, metabolic, gastrointestinal, cardiovascular, and endocrine problems. This area also includes studies of the biochemistry of uremia, nutritional/metabolic studies, and uremic toxicity. Investigations are directed to determine the causes of the abnormalities, underlying mechanisms of disease, and potential therapeutic procedures for treating or preventing such complications.

2. Renal Transplantation

These research projects are devoted to improving the methodology of renal transplantation and reducing the complications of patients utilizing this therapy. Studies cover such technical areas as organ preservation, immunosuppressive therapies, medical/surgical complications of transplantation, and applied transplant immunology specific to the renal area. Through better tissue matching, organ preservation, and improved understanding of immune related phenomena and of immunosuppressive regimens, increased functional graft and patient survivals are made possible. Another goal of research is to reduce complications of the transplanted patients.

3. Maintenance Therapies for End-Stage Renal Disease Patients.

Studies in this area are directed toward improving the effectiveness of chronic renal disease maintenance therapies to preserve residual renal function, as well as minimize complications inherent to both: the therapeutic interventions as well as the progressive renal insufficiency itself. Projects range over a broad area of applied research in dietary interventions, maintenance, dialysis therapy which includes hemodialysis, peritoneal dialysis, hemofiltration and their complications, as well as development or refinement of existing methodologies. Selected epidemiological studies are also devoted to the evaluation of maintenance therapies by collection of clinical and basic demographic data and other relevant information.

B. Overview of Research Progress

Pathophysiology of Chronic Renal Failure

A continuing long-range interest in this area is to clarify the functional characteristics of the chronically diseased kidney; in particular, to define: (a) changes in sodium, magnesium, phosphorus and hydrogen ion reabsorption and secretion by surface and deep nephrons and collecting ducts, as renal mass decreases; (b) biochemical alterations which occur in membrane phospholipids and fatty acids released from the kidney in response to different renal injuries; i.e., ischemia, glycerol induced renal failure, mercuric chloride, etc.; (c) mechanisms for which prolonged ureteral occlusion may lead to progressive loss of renal function and why the degree of recovery after relief of the obstruction is inversely related to the duration of the obstruction; (d) parathyroid hormone (PTH) metabolism by bone, kidney and liver, as well as events occurring in the cell by PTH action and alterations in PTH secretion observed in chronic renal failure; (e) the effect of classical and newly described neurotransmitters; i.e., alpha and beta adrenergic agonists, dopamine, acetylcholine, gamma amino-butyric acid, L-glutamine, lysine, serotonin, etc. on salt and water reabsorption by the renal tubules (1).

Studies of glomerular function in experimental diabetes are ongoing to test the hypothesis that there is a direct linkage between vasoactive hormones binding, altered glomerular hemodynamics and structurally defined glomerulopathy. Evidence from this and other laboratories indicates that a significant relationship between the diabetic state, glomerular functional abnormalities, and progressive diabetic glomerulopathy exists. Preliminary data utilizing in-vivo micropuncture techniques combined with in-vitro studies indicate that glomerular capillary hypertension and hyperfiltration occur in moderately, but not in strictly, controlled diabetic rates. Moderately hyperglycemic rats had single nephron hyperfiltration, while strictly controlled diabetic rats had values of single nephron glomerular filtration rate not different from normal controls. The present data suggest that glomerular pathology, considered to be preventable with strict glucose control, may be due to prevention of diabetic intrarenal hypertension, hyperperfusion and hyperfiltration. Other preliminary experiments suggest that diabetes is associated with decreased activity of sodium-mediated glucose transport, an effect corrected with insulin (2).

In studies of the antigenic constituents of diabetic basement membranes (BM), through recently developed hybridoma-derived monoclonal antibody techniques, renal BM appears to be heterogeneous with respect to certain glycoprotein and collagen antigens. Preliminary data indicate that in early and moderate stages of the disease, polyantigenic expansion of all immunohistopathologic components of mesangium, glomerular BM, and tubular basement membrane, are observed. In late stages, there is a diminution of all these antigens in the mesangium. Additionally, antigens are observed in the mesangium, which are normally only present in fetal but not in adult mesangium. These data document the complexity of polyantigenic alternations in the development of diabetic nephropathy (3).

Studies are in progress on the nature and components of biological control systems concerned with maintenance and homeostasis of sodium, potassium, magnesium, and phosphate under normal renal function and in chronic renal diseases, basically to study the effects of intrinsic renal disease on the function

of the involved kidney and the extrarenal effects of the chronically diseased kidney, on the body in which it resides (4).

Research focused on the metabolic perturbations occurring in animal models with chronic renal disease (CRD) after an acute challenge are continued to uncover physiologic compensating and regulatory mechanisms. Special emphasis is placed on nervous system contributions; i.e., the catecholamines and alpha and beta mediated effect. Preliminary studies on the non-ionic control of parathyroid hormone (PTH) secretion in CRD indicates that a vitamin D metabolite, 24, 25 dihydroxycholecalciferol and a histamine H₂ receptor antagonist, cimetidine, separately induce dramatic reductions in circulating PTH, independent of changes in serum ionized calcium. If these studies are confirmed, new medical approaches to the treatment of uremic hyperparathyroidism can be envisioned (5).

Investigation on the mechanisms of enhanced formation of glomerular basement membrane material in early experimental diabetes in rats is ongoing. Preliminary data indicate (a) that the increased glomerular basement membrane results from enhanced synthesis of complex glycoproteins which require uridine diphospho-(UDP)-sugars as the source of carbohydrate groups; (b) that the exaggerated formation of uracil ribonucleotides from orotate induced by experimental diabetes is prevented by insulin administration; (c) that the exogenous and/or endogenous supply of orotate critically modulates glomerular uracil ribonucleotide synthesis in diabetes. These results support the postulate that insulin deficiency causes a rapid increase in the glomerular synthesis and turnover of UDP-sugars and UDP-aminosugars which may facilitate the accumulation of basement membrane material soon after the onset of diabetes (6).

In studies aimed at investigating the possible role of insulin in modulating glomerular hemodynamics, the contractile response of mesangial cells to angiotensin II in media of different glucose/insulin concentration was studied, and it was found that insulin may modulate the contractile response activity by mesangial cells in low- or non-insulin conditions which could lead to a marked increase in glomerular blood flow, ultimately resulting in glomerulosclerosis (7).

Research efforts are ongoing to define the dose response relationship between plasma insulin concentration and insulin mediated glucose utilization, and whether insulin resistance universally found in uremic individuals is the result of receptor or postreceptor abnormalities. In order to determine whether insulin resistance could be overcome by very high insulin levels, the dose-response relationship between plasma insulin concentration and insulin-mediated glucose uptake in chronically uremic and control subjects were evaluated. Despite the higher steady state plasma insulin levels in uremics, the uptake of glucose was reduced by 50% compared to controls. These results indicate that the in vivo dose-response curve relating plasma insulin concentration to glucose metabolism is shifted to the right in uremic patients and fails to normalize at high insulin levels. Basal hepatic glucose production was similar in uremic and control subjects. In another set of studies to evaluate insulin's role in regulating amino acid metabolism in uremics, a significant generalized decrease in the release of all amino acids, with the exception of alanine and cystine, following insulin was found. These results are indicative that insulin-mediated glucose metabolism is severely impaired in patients with chronic renal insufficiency and that the primary site of insulin resistance resides in peripheral tissues, muscle (8).

A multicenter clinical study to evaluate the effects of 1,25 dihydroxy-Vitamin D₃ on growth of children with mild to moderate renal insufficiency (GFR 20-60 ml/min/ 1.73m²) in a double blind randomized clinical trial has been initiated. The goal of the study is to assess the long-term efficacy and safety of 1,25 (OH)₂ D₃ therapy in children with chronically progressive renal disease when compared with the conventional therapy with dihydrotachysterol (9).

Renal Transplantation

Research work including basic and clinical protocols to prevent organ destruction, counteract infection, and maximize rehabilitation proceed, including: the evaluation of Cyclosporine for immunosuppression; characterization of T-cell clones in organ rejection; lymphocyte glycolytic enzymes as markers for rejection; complement activation in kidney allograft rejection; total lymphoid irradiation vs. Cyclosporine for re-transplantation in patients who have rapidly rejected previous transplant on conventional immunosuppression; prevention and treatment of CMV infections; immune defects in organ transplant recipients with Epstein Barr virus and infection and antifungal prophylaxis (10).

A Program Project has been recently initiated to study methods to foster induction of tissue transplantation tolerance in humans through the development of collaborative protocols applying new technical advances in basic immunology, which includes monoclonal antibodies and T cell cloned human suppressor cells. Preliminary data suggest that preparation of cadaver renal transplant recipients with total lymphoid irradiation and anti-thymocyte globulin, can reduce, or perhaps eliminate, the requirement for chronic immunosuppression (11).

A pilot study to define the pharmacokinetics and establish dose-regimens of CMV immune globulin in renal transplant patients with high risk of primary infection is underway. Close to 100 potential transplant recipients with seronegative antibody titers to CMV have been screened for enrollment in the study (12).

In studies designed to further define the immunopathology of renal allograft rejection, based on improved methods for fractionation of peripheral blood cells and cell surface radiolabeling techniques, surface protein maps of blood vessel wall cells and circulating blood cells are being completed. These maps show large numbers of, as yet, unidentified proteins displayed on cell surfaces. The maps will allow (a) to distinguish which surface proteins are shared or are unique among cell types, and (b) to begin to identify specific spots as reference protein markers utilizing monoclonal antibodies to surface antigens (13).

Studies to evaluate the role of donor specific transfusions (DST) to enhance outcome of renal transplantation are ongoing. Thirty-five potential renal allograft recipients received DST under immunosuppressive coverage. The actuarial graft survival for these patients was 92% at 1 and 2 years which is similar to HLA identical sibling transplants (historical controls). The results were significantly better than the actuarial graft survival rate in one haplotype disparate sibling transplants (58%) at 1 and at 2 years (53%) (14).

To obtain long-term kidney preservation, research efforts continue to provide a detailed description of the biochemical and physiological changes that occur during hypothermic perfusion, and to develop appropriate methods to suppress or correct them. A perfusate which is devoid of albumin has been developed where the oncotic support is provided by hydroxethyl starch dissolved in the gluconate based perfusate. Long-term preservation of kidney results in loss of ATP and other nucleotides, evident especially between 3-5 days. It is postulated that maintenance of high levels of adenosine in the perfusate, and flushing the kidney with an adenosine deaminase inhibitor at room temperature prior to perfusion, enhances preservation (15).

Maintenance Dialysis Therapy

A National Cooperative Dialysis Study charged with developing techniques by which dialysis could be prescribed on a quantitative individualized basis compatible with providing the minimum exposure and keeping patients free from dialysis related complications was completed this year. The lead center was located at Harvard University and functioned under the direction of a principal investigator and an executive committee; nine centers participated in the study. Urea kinetics based on a mathematical approximation of the kinetics of urea balance over time was the method utilized to control therapy. Patients were randomized into four treatment groups divided along two dimensions: dialysis treatment time (long or short) and blood urea nitrogen (BUN) concentration averaged with respect to time (high and low). Results indicated that there was not difference in mortality between the groups. Withdrawal of patients from the high-BUN groups for medical reasons was significantly greater than withdrawal from the low-BUN groups. Hospitalization was also greater in the high-BUN groups, but dialysis treatment time had no significant effects. It was concluded that the occurrence of morbid events is affected by the dialysis prescription. Increased morbidity appears to accompany prescriptions associated with a relatively high BUN. Conversely, morbidity may be decreased by prescriptions associated with more efficient removal of urea if the dietary intake of protein and other nutrients is adequate (16-17).

A longitudinal study involving hemodialysis patients randomly assigned either to an immediate endurance exercising training program or to a sedentary control group has been completed. Exercise training resulted in: improved lipids profile, glucose metabolism and hematological functions, lower blood pressure and lesser requirements for anti-hypertensive drugs together with increased level of physical fitness. Participation in aerobic endurance exercise programs seems to improve some of the metabolic abnormalities observed in ESRD patients on maintenance hemodialysis, and may reduce the risks for cardiovascular complications. Further clinical, as well as experimental, studies should verify these observations and elucidate the basic mechanisms leading to the beneficial changes observed (18).

A long term prospective study is underway at the Karolinska Institute (Sweden), to determine the adequacy and metabolic effects of continuous ambulatory peritoneal dialysis (CAPD), and to assess its future role in maintenance dialysis treatment. It includes studies on transperitoneal transport, clearance and various effects on endogenous middle molecules. Forty uremic patients are undergoing CAPD under this program. Preliminary data indicate that the episodes of peritonitis have decreased gradually over time, while progress of peripheral neuropathy in 15 non-diabetic patients, after 10-15 months of CAPD, has increased. Nitrogen-balance has been positive, including in patients with dietary protein intake less than 1.0 gram per day. Ratios of amino acids such as tyrosine/phenylalanine and glycine/valine have been found to be normal, in contrast to either untreated uremic patients, intermittent peritoneal dialysis patients or hemodialysis patients. Glucose tolerance and immunoreactive serum insulin response to oral glucose loads have not changed before, 2-6 months after, and after 12-16 months on CAPD. Serum triglycerides (TG) and cholesterol levels, including very low density lipoprotein (VLDL) and low density lipoprotein (LDL) fractions, are found to be increased; in 75% of cases these changes are more marked after 2-4 months on CAPD than 12 months later. In 25% of the patients, VLDL/TG continues to rise to higher levels at the 12 months' followup.

A significant correlation has been established between the daily supply of glucose from the dialysis fluid and the serum TG levels (19).

Operation of a National CAPD Patients Registry as an interim measure for generating data to assist in the evaluation of this maintenance therapy is conducted through a Contract with the University of Missouri - Columbia as the Clinical Coordinating Center and the Emmes Corporation of Potomac, Maryland as the Data Coordinating Center. Implementation of the registry on a nationwide basis began July 1, 1981. Such a program was needed to provide basic information regarding the characteristics of patients receiving such therapy, distribution of centers offering it, and selected outcome measures such as treatment-related complications (29).

References

1. Klahr, S. 5 P01 AM 09976-18, Washington University,
"Pathophysiology of Renal Disease and Uremia"
2. Brenner, N. M. 1 R01 AM 30410-01 Brenner, N.M. Brigham and Women's
Hospital, "Glomerular Function in Experimental Diabetes Mellitus"
3. Michael, A. F. 5 R01 AM 26149-04 University of Minnesota
"Pathogenesis of Diabetic Nephropathy"
4. Bricker, N.S. 5 R01 AM 2609-04 University of California, Los Angeles,
"Homeostatic Mechanisms in Uremia"
5. Bourgoignie, J.J. 2 R01 AM 19822-06 University of Miami,
"Renal Failure: Pathophysiology and Possible Prevention"
6. Cortes, P. 5 R01 AM 28081-03 Henry Ford Hospital,
"Diabetic Glomerulopathy and Pyrimide Metabolism"
7. Kreisberg, J. I. 5 R01 AM 29787-02 University of Texas Health Science
Center at San Antonio, "Pathophysiology of Diabetic Glomerulosclerosis"
8. DeFronzo, R. A. 5 R01 AM 28045-02 Yale University,
"Glucose and Amino Acid Metabolism in Uremia"
9. Chan, J. C. 1 R01 AM 31370-01A1 Virginia Commonwealth University, MCV,
"Growth Failure in Children with Renal Diseases"

and

Carter, W. H. 1 R01 AM 32431-01 Virginia Commonwealth University, MCV
"Data Coordinating Center: Pediatric Renal Disease Study"
10. Najarian, J.S., 5 P01 AM 13083-15 University of Minnesota,
"Studies of Organ Transplantation in Animals and Man"
11. Strober, S. 1 P01 AM 32075-01 Stanford University,
"Use of Hybridomas and T Cell Clones in Transplantation"

12. Snyderman, D.R. 5 R01 AM 31389-01 Johns Hopkins University,
"Kidney Transplant Associated Cytomegalovirus Prevention"
13. Busch, George J.:5 R01 AM 26326-02, Brigham and Women's Hospital,
"Immunopathology of Renal Allograft Rejection"
14. Anderson, C. B. 5 R01 AM 27895-01 Washington University,
"Renal Transplant Enhancement by Donor-Specific Blood"
15. Belzer, F. O. 5 R01 AM 18024-07 University of Wisconsin, Madison,
"Studies in Organ Preservation"
16. Lowrie E.N 01 AM 6-2207 Harvard University,
"National Cooperative Dialysis Study"
17. Kidney International, "The National Cooperative Dialysis Study"
Volume 23 Supplement 13, April 1983
18. Goldberg, A. P.:N01 AM 9-2221 Washington University, St. Louis,
"Effects of Exercise Training on Lipid and Carbohydrate Metabolism and
Hemodialysis Patients"
19. Bergstrom, J., 5 R01 AM 27519-02, Karolinska Institute, Sweden,
"Protein, Carbohydrate, Lipids and Salt Metabolism in CAPD."
20. Nolph, K. N01 AM 3-2214, Missouri University,
"National CAPD Patients Registry," Clinical Coordinating Center

and

Novack, J. N01 AM 3-2245, Emmes Corporation, Potomac, Maryland,
"National CAPD Patients Registry," Data Coordinating Center

C. Selected Research Advances in Chronic Renal Disease/Renal Transplantation

1. PRETRANSPLANT BLOOD TRANSFUSIONS TO CONDITION POTENTIAL RENAL TRANSPLANT RECIPIENTS RESULT IN IMPROVED SUCCESS RATES OF KIDNEY TRANSPLANTATION

Background

A few years ago, Terasaki and Opelz called attention to the fact that the yearly success rates of kidney transplantation in North America had declined from 1968 to 1975 despite improvements in immunosuppression, histocompatibility testing, organ harvesting and preservation, and overall clinical experience acquired over those years (1-2). It was postulated that withholding transfusions from patients undergoing dialysis resulted in the declining transplant success rates (1); evidence shows that recovery from the previous downward trend seems largely attributable to the adoption of a pretransplant transfusion policy for more centers (3-4).

Advance

Recognition that multiple pretransplant blood transfusions significantly improve kidney transplant outcome has raised graft and patient survival rates throughout the world, and it represents one of the most significant advances in the clinical management of renal transplantation.

The exact mechanism(s) responsible for the allograft protection induced by pretransplant blood transfusions, in cadaver as well as in living-related donor transplant patients, remains unknown, and it might be a composite of several mechanisms. Preliminary data (5-9) indicate that blood transfusions work by (a) the active induction of prolonged immunologic unresponsiveness or tolerance specific to, and/or nonspecific to, donor antigens; (b) altered host immunologic competence due to induction of suppressor cells; (c) production of varying populations of antibodies, including anti-B cells, enhancing, or antiidiotypic-antibodies.

Antibodies in addition to classical anti-HLA and B may be generated after blood transfusion. While pretransplant donor-specific anti-HLA A and B antibodies may be deleterious to graft outcome, other types of antibodies may have beneficial effects. Conclusive data for an active antibody-mediated enhancement mechanism in the clinical situation are not available; nonetheless, preliminary data from ongoing research indicate that: identification of antiidiotypic (anti-anti HLA) antibodies in the sera of post-blood transfusion patients who had no demonstrable anti-HLA response to transfusions had been successfully obtained (5-7); anti-IgG antibodies were generated post blood transfusions and, when present, were associated with marked improvement in allograft survival (8); antibodies capable of inhibiting responses in MLC (mixed lymphocyte culture) were induced by blood transfusions (9); blood transfusions did induce antibodies directed against T-cell antigen-specific receptors, via antiidiotypic antibodies (9).

Significance

However many basic questions remain unanswered, there is general agreement that pretransplant blood transfusions significantly improve the outcome of cadaver, as well as living-related, kidney transplants.

Future Directions

Basic research work should proceed with the aim of developing specific pretransplant immunotherapeutic protocols that will further enhance the outcome and will make possible kidney transplantation to those individuals highly "sensitized", and therefore, at present, not candidates for renal transplantation.

References

1. Terasaki, P.I., Opelz, G., et al.: Analysis of Yearly Kidney Transplant Survival Rates. Transplant Proc. 8:139, 1976.
2. Opelz, G., Sengal, D.P.S., et al: Effect of Blood Transfusions on Subsequent Kidney Transplants. Transplant Proc. 5:253, 1973.
3. Opelz, G., and Terasaki, P.I.: Importance of Pre-operative Transfusions for Cadaver Kidney Transplants. Transplant. 31:106, 1981.
4. Corry, R. J.: 5 RO1 AM 29863-03, Univ. of Iowa, Iowa City, "Mechanisms of Transfusions in Improving Allograft Survival."
5. Jordan, S.C.: 1 K04 AM 01183-01, Univ. of California, Los Angeles, "Induction of Antiidiotypic Antibodies by Pre-Transplant Transfusions."
6. Jordan, S.C., Barkely, D.C., et al: Induction of Antiidiotypic Antibodies by Pre-transplant Blood Transfusions. Presented, Society for Pediatric Research, Washington D.C., May 1983.
7. Ettenger, R.B.: 5 R01 AM 31501-02, Univ. of California, Los Angeles, "Immunological Effect of Transfusion of Renal Transplants."

8. Chia, D., Hermi, T., Terasaki, P., et al: Transplant. Proc. 14:372, 1982.
 9. Singal D.P., Joseph S., et al.: Transplant. Proc. 14:316, 1983
2. RENAL ALLOGRAFT SURVIVAL RATES SLIGHTLY BETTER IN CYCLOSPORINE TREATED RENAL GRAFT RECIPIENT AS OPPOSED TO THOSE RECEIVING CONVENTIONAL IMMUNOSUPPRESSION

Background

As a result of a better understanding of histocompatibility systems, utilization of pretransplant blood transfusions to precondition potential renal transplant recipients, improved preservation techniques, and better selection of patients, a decline in morbidity and mortality associated with renal transplantation has been observed in recent years. Overall graft survival has not really improved in the past decade, but we may be at a turning point in the history of transplantation, armed with new information about immunogenetics of rejection and new modes of therapy.

Cyclosporine (CsA) is a potent immunosuppressant agent used in the prevention of allograft rejection, which is derived from the fermentation broth of the fungus *Trichoderma polysporum*. Its immunosuppressive activity was first discovered by Borel et al (1) in Basel, Switzerland. Subsequent extensive experimental studies in the rat, dog, rabbit, etc. revealed a strong immunosuppressive activity without bone-marrow suppression (2). Promising experimental results led Calne et al (Cambridge, UK) to first initiate a clinical trial using CsA as the sole immunosuppressive agent in renal transplantation. Rejection prophylaxis did occur but an unexpectedly severe nephrotoxicity was responsible for a high incidence of early non-functioning grafts (3). Furthermore, the addition of other immunosuppressants to CsA lead to an unacceptable high infection rate (4). Further clinical experience and the extension of these initial pilot studies to prospective randomized clinical trials (5-7) with modifications of the original immunosuppressive protocols, provide the necessary scientific format for the ongoing objective evaluation of the efficacy, safety and possible toxic side-effects of CsA.

Increased interest and increased enthusiasm have evolved with the availability of CsA in the immunopharmacology armamentarium of renal transplantation.

Advance

Results in clinical trials.

Since the initial trial by Calne et al in 1978, every clinical series has demonstrated that CsA treatment induces graft survival at least as good as any other immunosuppressant regimen.

Discrepancies exist between published results obtained from collective data analysis derived from clinical studies conducted in European, Canadian, and American transplant centers. Some of the data indicate dramatic improvement in patient, as well as graft, survival rates with CsA treated patients compared to patients on standard immunosuppressive regimens. These data should be read and interpreted with extreme care since in the majority of cases a comparison is established between actual CsA treated patients vs. either data retrospectively obtained from "historical controls" or derived from prospective randomized trials involving very different treatment protocols selected "individually" at each participating center for the standard-immunosuppression control group.

The interim analysis of an ongoing prospective randomized controlled clinical trial (8) of CsA plus low doses steroids (Prednisone) vs. the standard immunosuppressive regimen of Prednisone and Azathioprine (AZA) plus antilymphocyte globulin (ALG) in the immediate post-transplant period, demonstrate no significant statistical difference in patient or graft survival rates when the two groups are compared, (5-6, 8). Actuarial overall patient and graft functional survival rates up to 26 months post-transplant, in all CsA and standard immunosuppression renal graft recipients, show that renal allograft survival rates are only slightly better (by 7% at 1 year) in CsA-prednisone than in AZA-prednisone-ALG treated renal allograft recipients. Patient survival rate is slightly better in the conventional treatment group (by 3% at 1 year). None of the differences between groups or in the subgroups are statistically significant (all p values are $\geq .1$).

Significance

Some of the disadvantages associated with the use of CsA as opposed to the conventional regimen include: a longer duration of acute tubular necrosis -- if it occurs -- in CsA treated patients, higher creatinine levels at all times post-transplant, and more difficult management of hypertension and hyperkalemia (increased serum potassium levels). The advantages to the use of CsA include: fewer viral and bacterial infections, shorter hospitalization times, and fewer rejection episodes.

Therefore, even though it is possible for other trials to show a marked advantage of CsA over the conventional immunosuppressive regimen, it is important to realize that when certain features are incorporated to the standard immunosuppression regimen, such as patients being heavily transfused, splenectomized, and receiving ALG, graft survival rates can be maximized (8).

Future Directions

As indicated earlier, clinical studies have shown CsA to be effective in the prevention of allograft rejection, but how this immunosuppressive effect manifests itself at the cellular and intercellular level, as well as the metabolism, pharmacokinetics, and immunosuppressive action, is unknown and needs further investigation. Further analysis will be necessary to determine which regimen is superior in terms of safety as well as efficacy for long-term maintenance of renal allograft function, and which is the most cost-effective one.

References

1. Borel, J.F., et al: Biological effects of Cyclosporine A: A new antilymphocytic agent. *Agents Action* 6:468, 1976
2. Calne, R.Y., et al: Cyclosporin A initially as the only immunosuppressant in 34 recipients. *Lancet* 2:1033, 1979
3. Cyclosporin A as sole immunosuppressive agent in recipients of kidney allografts from cadaver donors: Preliminary results of a European Multicenter Trial. *Lancet* 2:57, 1982
4. Calne, R.Y.: Immunosuppression for organ grafting. *Transplant Proc.* 12:239, 1980
5. Ferguson, R.M. et al.: Cyclosporin A in renal transplantation: A prospective randomized trial. *Surgery* 92:175, 1982
6. Najarian, J.E., et al.: A prospective trial of the efficacy of Cyclosporine in renal transplantation at the University of Minnesota. *Transplant. Proc.* 15:438, 1983
7. The Canadian Multicenter Transplant Study Group: A randomized clinical trial of Cyclosporine in cadaveric renal transplantation. *N.Eng. J. Med.* 14:809, 1983
8. Najarian J.S.: 5 P01 AM 13083-16, "Studies of Organ Transplantation in Animals and Man"

3. POTENTIAL BENEFICIAL EFFECTS OF NITROGEN FREE ANALOGUES OF ESSENTIAL AMINO ACIDS IN THE TREATMENT OF CHRONIC RENAL DISEASE MAY EXCEED THOSE PRODUCED BY ESSENTIAL AMINO ACIDS.

Background

The basic principle for the management of renal insufficiency is the restriction of protein, and the energy requirement being supplied from carbohydrate and fat. In patients with chronic renal failure, the institution of a protein-poor diet results in an improvement of the general condition, disappearance of uremic symptoms, and a decrease in serum urea concentration. The more the renal function deteriorates, the more the intake of proteins has to be restricted, leading often to the common clinical observation of progressive malnutrition or wasting, secondary to protein depletion. It seems clear that accumulation of nitrogenous metabolites play a major role in the pathogenesis of the uremic syndrome. Several recent studies suggest that nutritional or metabolic factors may also affect the rate of progression of renal disease. The evidence, although not conclusive, indicates that low protein diets, particularly when associated with careful control of phosphorus and calcium intake, may retard the rate of progression of renal failure in animals and humans.

Nitrogen free branched-chain keto analogues (BCKA) of essential amino acids have been utilized for treatment of chronic renal failure, liver insufficiency, and certain genetic diseases (1-5), since these compounds lack the alpha-amino nitrogen and are rapidly converted to amino acids. Therefore, administering them may be almost tantamount to giving amino acids without increasing the nitrogen load. Information, nevertheless, is lacking on the in-vivo effect of branched-chain amino acids (BCAA) and their BCKA on intermediary metabolism; extent of in-vivo oxidation and transamination of BCKA relative to BCAA; tissue and biological fluids concentration, and inter-organ transport; hormonal regulation; interplay with other amino acids and the extent of utilization of these compounds for protein synthesis.

Advance

Nitrogen free (BCKA) can replace (BCAA) in the diet of animals and man though not with complete efficiency.

Over the past few years several investigators, independently, have developed methods designed to answer some of the questions outlined above (6-12). BCAA and BCKA metabolism in man and the conscious dog is being investigated by using isotopic and arterio-venous difference techniques (7). While isotopic, tracer methods measure total body flux of substrates in and out of a central pool, the A-V difference technique measures the net contribution of various tissues to the flow of substrates from one organ to another. The combination of both techniques allows for measurements of the relative contributions of the different organs to total body flux. These data indicate that approximately 30 percent of the flux in the overnight fasted conscious dog occurs across the splanchnic tissues; half by the "gut" and half by the liver. Skeletal muscles produce (BCAA) (leucine) in the post-absorptive period. The net flow of (BCKA) leucine is from

peripheral to visceral tissues. Therefore, the liver, "gut," and kidneys equally utilize BCKA while skeletal muscles supply that amount. The dilution of label across the "gut" is due to an exchange of label for unlabeled BCAA-leucine molecules, while the dilution across the liver is partially (1/3) due to exchange and partially (2/3) to net addition to BCAA.

In another set of investigations (6) to estimate the extent, as well as the relative rate of incorporation, of BCKA vs BCAA into newly synthesized protein, ^{14}C -labelled BCKA-(leucine) and ^3H -labelled-BCAA (leucine) were administered simultaneously intragastrically to normal rats and normal human volunteers. The mean incorporation ratio in protein or various rat organs varied from a high of 0.42 (in muscle) to a low of 0.22 (in liver). Whole body protein incorporation ratio averaged 0.30.

Normal volunteers (x7) were given the isotopes by constant intragastric infusion for 6 hours (6). Mean ratio of relative incorporation into: plasma albumin (0.64) and fibrinogen (0.63) became constant after the third hour, and was indistinguishable from one another; (this finding is consistent with the possibility that both proteins are synthesized from a common precursor pool of amino acids); plasma IgG was 0.68; in red blood cell globulin was 0.81 and plasma leucine averaged 0.62.

The results of these studies show that the extent, as well as rate, of incorporation of labelled BCAA and BCKA into newly synthesized protein can be simultaneously quantitated in animals and man and that there is a reduced nutritional efficiency of BCKA relative to BCAA. The probability of a BCKA molecule becoming incorporated into newly formed protein depends on a series of complex steps; these include, among others: transport, oxidation and transamination processes, protein synthesis and degradation in the organ where protein synthesis takes place, as well as within the organ where it is measured.

Significance

In-vivo essential amino acid kinetics are not that well known. Synthesis and protein breakdown calculations as usually done do not represent whole amino acid kinetics in-vivo. Preliminary results of ongoing studies indicate that the extent, as well as rate, of incorporation of labelled BCAA and BCKA into newly synthesized proteins can be simultaneously quantitated both in normal animal and normal man. The techniques described do not directly measure the nutritional efficiency of Nitrogen-free BCKA as substitutes for the corresponding essential amino acids, but they yield an estimate of (a) the extent of incorporation of labelled BCKA relative to labelled BCAA into individual protein, (b) the net contribution of various tissues to the flow of substrates from one organ to another, and (c) the inter-organ transport of leucine carbon skeletons, and (d) the source of this essential amino acid for protein synthesis in various organs.

Future Directions

Further studies along these lines, coupled perhaps with mass-spectrometric techniques, should be indicated to further the understanding of the metabolism/catabolism and overall in-vivo behavior of nitrogen free BCKA in promoting stimulation of protein synthesis, inhibition of protein degradation, and

overall nitrogen balance. The aim of pursuing this research work is to further define the potential role and relevance of nitrogen free analogues of essential amino acids in the treatment of progressive renal disease, uremia, and serious liver diseases among others.

References:

1. International Symposium on Branched-Chain Amino and Keto Acids in Health and Disease- Gottingen, F.R., Germany, October 20-23, 1983, Proceedings, In Press.
 2. Conn, H. Oral BCAA vs Dietary Protein in Chronic Protal Systemic Encephalopathy: Results of a Multicenter Randomized Central Trial - In (1).
 3. Sapir, D.G., Walser, M., et al. Effects of aopha-Ketoisocaproate and of Leucine on Nitrogen Metabolism in Post-Operative Patients. Lancet 1: 1010, 1983.
 4. Mitch, W.E., Abras, E., et al.: Long-term Effects of a New Ketoacid-amino acid Supplement in Patients with Chronic Renal Failure - K. Int. 22: 48, 1982.
 5. Gretz, N., Korb, E., et al.: Low Protein Diet Supplemented by Keto-Acids in Chronic Renal Failure: A Prospective Controlled Study. K. Int. In Press.
 6. Munoz, S., Walzer, M. Incorporation of Enterally Administered Ketoleucine and Leucine into Proteins in Normal Animal and Man. In Press.
 7. Abumrad, N. Effect of Branched-Chain Amino Acids and Their Keto analogues on Intermediary Metabolism In Vivo. In (1).
 8. Adibi, S.A. Overview of Biochemical, Physiological and Clinical Importance of BCAA. In (1).
 9. Morgan, H.E. Leucine and Regulation of Protein Synthesis and Degradation. In (1).
 10. Williamson, J.R. Alpha-Keto Isovalerate Metabolism in Liver and Interaction with other Pathways. In (1).
 11. Felig, Ph. Inter-organ flux of BCAA and BCKA. In (1).
 12. Bier, D.M. Effect of Dietary Protein and Energy Intake on Utilization of BCAA for Protein Synthesis. In (1).
- 1 R01 AM 32008-01 - Walser, M. Keto-Acid Therapy in Renal Failure. Johns Hopkins University.
- N01 AM 9-2220. Kopple, J.D. Dietary Maintenance of Chronic Uremic Patients. Harbor-UCLA Medical Center.

D. Implementation Plan

Request for Proposals (RFPs)

1. Continuous Ambulatory Peritoneal Dialysis, National Patients Registry.

Two RFPs for re-competing this project were released during fiscal year 1983: the first for continuing the operations of the Clinical Coordinating Center, the second to operate the Data Coordinating Center. Both contracts were awarded during fiscal year 1983.

2. Request for Applications (RFAs)

A Request for Applications for a Cooperative Agreement Program (RFA-NIADDK-83-1) for a multicenter "Cooperative Clinical Study of Dietary Modification on the Course of Progressive Renal Diseases" has been prepared and issued in fiscal year 1983 (attached). The aim of this initiative is to ascertain whether or not dietary factors such as protein/phosphate restriction may influence the rate of progression of chronic renal diseases irrespective of the nature of the primary disease process. It is anticipated that approximately 10 clinical centers will participate in each phase of the study. The clinical centers will work in conjunction with a data coordinating center, being sought under a separate competition (RFA-NIADDK-84-AM-02).

The National Center for Health Services Research (NCHSR) and the Health Care Financing Administration (HCFA) will be simultaneously conducting a study of the cost-effectiveness of dietary intervention in chronic renal failure. The NIADDK expects that representatives of the NCHSR and HCFA will participate with the clinical centers and the data coordinating center and NIADDK staff.

C. ESRD NETWORK ORGANIZATIONS

Introduction

The objectives of the ESRD program are to promote high quality care and the efficient distribution of resources in the delivery of kidney dialysis and transplantation services. Section 1881(c) of the Social Security Act authorized the establishment and support of network organizations to accomplish this purpose. There are 32 network organizations composed of representatives from each dialysis and transplant facility as well as at-large members representing ESRD patients and professional disciplines (such as social workers, nurses, dieticians, etc.) involved in the delivery of ESRD services. Total funding for the Networks during 1983 was \$4.8 million.

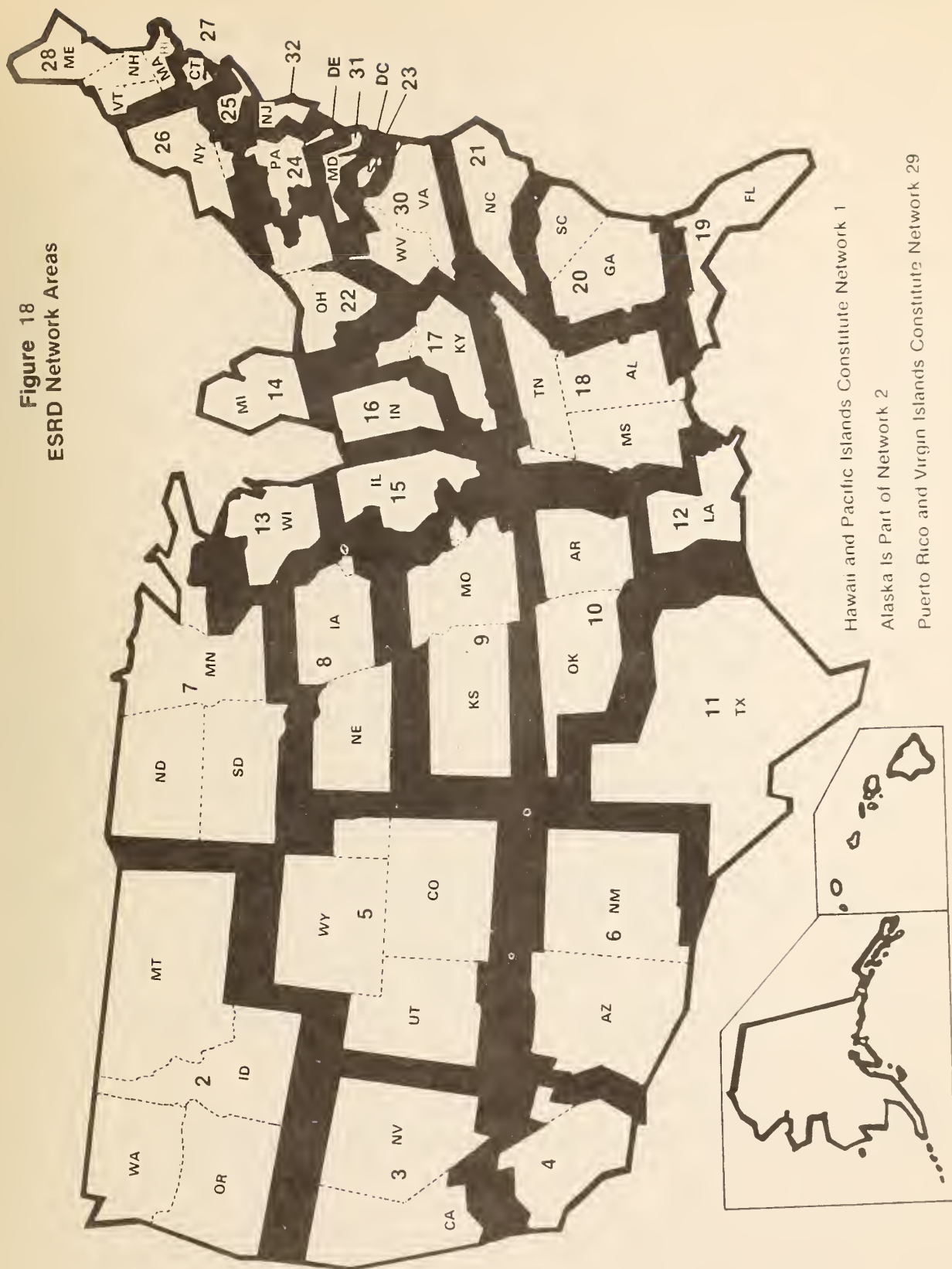
Accomplished

Network efforts during 1983 focused on quality assurance, data collection, rehabilitation of patients, and special studies in each of the networks on various aspects of ESRD.

Quality assurance studies undertaken by the networks in 1983 include trend analyses and comparative survival statistics of dialysis and transplantation, pediatric and adolescent treatment therapies, patient rehabilitation, patient care planning, dialyzer reuse, hepatitis incidence and prevalence, selection of various treatment modalities, hospitalization stays, CAPD trends, as well as other morbidity and mortality studies. HCFA has other quality assurance mechanisms in place which could replace piecemeal network efforts and which would enhance efforts to refine national policy on ESRD.

Data management also continues to be a major thrust of the networks. Patient tracking systems have been implemented in all networks which have enhanced their ability to validate data. However, collection of patient-specific data can be coordinated more efficiently by HCFA, using regional offices and State resources.

Figure 18
ESRD Network Areas



D. APPENDIX - TABLES AND FIGURES

Table 1	ESRD Facilities Surveyed and Reporting by State
Table 2	Minimum Utilization Rate Status - Transplant
Table 3	Annual Distribution of Self-Care Dialysis Patients
Table 4	Patients Receiving Care As of 12/31/83
Table 5	Number and Percent Increase of Dialysis Patients
Table 6	Transplants Performed During 1983 - By State
Table 7	Range of the Numbers of Transplants Performed for 1983
Table 8	ESRD Network Distribution of Transplants Arrayed by Number of Transplants Performed
Table 9	Charges, Estimated Reimbursements and Average Length of Stay for Transplants and Nontransplant Hospital Stays: 1981
Table 10A	Kidney Acquisition Charges - Average and Range for Living Related Donor Kidneys for 1983 By Region
Table 10B	Kidney Acquisition Costs - Average and Range of Estimated Costs for Living Related Donor Kidneys for 1983 by Region
Table 11A	Kidney Acquisition Charges - Average and Range of Estimated Costs for Cadaveric Donor Kidneys for 1983 By Region
Table 11B	Kidney Acquisition Costs - Average and Range of Estimated Costs for Cadaveric Donor Kidneys for 1983 By Region
Table 12	1983 Kidney Acquisition Costs Reported By Independent Organ Procurement Agencies by Region
Table 13	Estimated Enrollment and Aggregate Benefit Payments on a Cash Basis, Total ESRD Medicare Program
Table 14	Estimated Income to Medicare Generated by ESRD Second Payer Regulation
Table 15	Survival of Dialysis Patients
Table 16	Patient Survival of Living-Related Renal Transplants

Figure 1	ESRD Program Growth
Figure 2	Number of Certified ESRD facilities
Figure 3	Dialysis Facilities, Hospital - 1983
Figure 4	Dialysis Facilities, Independent - 1983
Figure 5	Type of Ownership - Profit vs. Non-Profit, 1246 ESRD Dialysis Providers, 1983
Figure 6	Minimum Utilization Rate Status, Dialysis - 1983
Figure 7	Number of Patients in Each Dialysis Treatment Setting By Network - 1983
Figure 8	Home Dialysis Patients - 1983
Figure 9	Home Dialysis Modality - 1983
Figure 10	Home Patient Modalities (Hemodialysis, Peritoneal and CAPD)
Figure 11	Number of Chronic Dialysis Patients Being Treated By Medicare Certified Suppliers of ESRD Services in the United States By Treatment Setting, January 1979 - December 1983
Figure 12	Dialysis Setting 1982 - 1983
Figure 13	Number of Transplant Types By Network - 1983
Figure 14	Transplants 1982 - 1983
Figure 15	Patients Awaiting Transplants vs. Transplants Performed
Figure 16	Comparison By State of Exception Requests - 1983
Figure 17	Major Reasons for Changes in the Number of Patients Treated By Medicare Certified Suppliers of ESRD Services, 1979 - 1983
Figure 18	ESRD Network Areas

Table 17	Patient Survival of Cadaveric Kidney Transplants
Table 18	Graft Survival of Cadaveric Kidney Transplants,
Table 19	Graft Survival of Living Related Transplants
Table 20	Enrollees at Risk
Table 21	Ratio of Patients Trained for Home Dialysis and Dialysis Patients Transplanted to Average Number of Dialysis Patients

CMS LIBRARY



3 8095 00012346 9



**Department of
Health and Human Services**

Health Care Financing Administration

HCFA Pub. No. 02150